ELEVIDYS- delandistrogene moxeparvovec-rokl
Sarepta Therapeutics, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ELEVIDYS® safely and effectively. See full prescribing information for ELEVIDYS.

ELEVIDYS (delandistrogene moxeparvovec-rokl) suspension, for intravenous infusion
Initial U.S. Approval: 2023

WARNING: ACUTE SERIOUS LIVER INJURY AND ACUTE LIVER FAILURE

See full prescribing information for complete boxed warning.

- **Acute serious liver injury, including life-threatening and fatal acute liver failure, has occurred with ELEVIDYS. (5.1)**
- **Patients with preexisting liver impairment may be at higher risk. (5.1)**
- **Prior to infusion, assess liver function by clinical examination and laboratory testing. Administer systemic corticosteroids before and after ELEVIDYS infusion. Continue to monitor liver function weekly for the first 3 months after infusion and continue until results are unremarkable. (2.1, 2.2, 2.4)**
- **Instruct patients to maintain proximity to an appropriate healthcare facility, as determined by the healthcare provider, for at least 2 months following ELEVIDYS infusion. (2.1)**
- **Obtain prompt consultation with a specialist (e.g., gastroenterologist or hepatologist) if acute serious liver injury or impending acute liver failure is suspected. (2.2, 5.1)**

RECENT MAJOR CHANGES

Boxed Warning	11/2025
Indication and Usage (1)	11/2025
Dosage and Administration (2)	11/2025
Contraindications (4)	11/2025
Warnings and Precautions (5)	11/2025

INDICATIONS AND USAGE

ELEVIDYS is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients 4 years of age and older with Duchenne muscular dystrophy (DMD) who are ambulatory and have a confirmed mutation in the *DMD* gene. (1,12.2,14)

Limitations of Use:

ELEVIDYS is not recommended in patients with:

- Preexisting liver impairment (defined as gamma-glutamyl transferase [GGT] > 2 x upper limit of normal or total bilirubin > the upper limit of normal not due to Gilbert's syndrome) or active hepatic viral infection due to the high risk of acute serious liver injury and acute liver failure.
- Recent vaccination (within 4 weeks of treatment) due to immunogenicity and potential safety concerns.
- Active or recent (within 4 weeks) infections due to safety concerns.

DOSAGE AND ADMINISTRATION

ELEVIDYS is for single-dose intravenous infusion only.

- Select patients for treatment with ELEVIDYS with anti-AAVrh74 total binding antibody titers <1:400. (2.1)
- Postpone in patients with active or recent (within 4 weeks) infections. (2.1)
- Assess liver function, platelet counts and troponin-I before ELEVIDYS infusion. (2.1)
- Recommended dosage: 10 to 70 kg: 1.33×10^{14} vector genomes (vg) per kg of body weight; 70 kg or greater: 9.31×10^{15} vg. (2.2)
- One day prior to infusion, initiate a corticosteroid regimen for a minimum of 60 days. Recommend modifying corticosteroid dose for patients with liver function abnormalities. (2.2)

- Administer as an intravenous infusion over 1-2 hours. Infuse at a rate of less than 10 mL/kg/hour. (2.4)

DOSAGE FORMS AND STRENGTHS

- ELEVIDYS is a suspension for intravenous infusion with a nominal concentration of 1.33×10^{13} vg/mL. (3)
- ELEVIDYS is provided in a customized kit containing ten to seventy 10 mL single-dose vials, with each kit constituting a dosage unit based on the patient's body weight. (3)

CONTRAINDICATIONS

- ELEVIDYS is contraindicated in patients with any deletion in exon 8 and/or exon 9, including a deletion of any portion or the entirety of these exons, in the *DMD* gene. (4)

WARNINGS AND PRECAUTIONS

- Serious Infections: Serious infections with fatal outcomes may occur due to concomitant administration of corticosteroids, additional immunosuppressants, and ELEVIDYS. Monitor patients for signs and symptoms of infection; treat appropriately. (5.2)
- Myocarditis: Acute, serious, life-threatening myocarditis and troponin-I elevations have been observed. Monitor troponin-I before ELEVIDYS infusion, and weekly for the first month after ELEVIDYS infusion. (5.3)
- Infusion-related Reactions: Infusion-related reactions, including hypersensitivity reactions and anaphylaxis, have occurred. Monitor during administration and for at least 3 hours after end of infusion. If symptoms occur, slow or stop the infusion and give appropriate treatment. Once symptoms resolve, restart infusion at a slower infusion rate. Discontinue infusion for anaphylaxis. (2.4, 5.4)
- Immune-mediated Myositis: Severe to life-threatening immune-mediated myositis has been reported with ELEVIDYS in patients with deletions including portions of exons 1 to 17 and /or exons 59 to 71 of the *DMD* gene. Consider additional immunomodulatory treatment if symptoms of myositis occur (e.g., unexplained increased muscle pain, tenderness, or weakness). (5.5)
- Pre-existing Immunity against AAVrh74: Perform baseline testing for presence of anti-AAVrh74 total binding antibodies prior to ELEVIDYS administration. (5.6)

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥5%) were vomiting and nausea, liver injury, pyrexia, thrombocytopenia, and troponin-I increased. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Sarepta Therapeutics, Inc., at 1-888-SAREPTA (1-888-727-3782) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 11/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: ACUTE SERIOUS LIVER INJURY AND ACUTE LIVER FAILURE

- **Acute serious liver injury, including life-threatening and fatal acute liver failure, has occurred with ELEVIDYS *[see Warnings and Precautions (5.1)].***
- **Patients with preexisting liver impairment may be at higher risk *[see Warnings and Precautions (5.1)].***
- **Prior to infusion, assess liver function by clinical examination and laboratory testing. Administer systemic corticosteroids before and after ELEVIDYS infusion. Continue to monitor liver function weekly for the first 3 months after infusion and continue until results are unremarkable *[see Dosage and Administration (2.1, 2.2, 2.4)].***
- **Instruct patients to maintain proximity to an appropriate healthcare facility, as determined by the healthcare provider, for at least 2 months following ELEVIDYS infusion *[see Dosage and Administration (2.1)].***
- **Obtain prompt consultation with a specialist (e.g., gastroenterologist or hepatologist) if acute serious liver injury or impending acute liver failure is suspected *[see Dosage and Administration (2.2), Warnings and Precautions (5.1)].***

1 INDICATIONS AND USAGE

ELEVIDYS is indicated for the treatment of patients 4 years of age and older with Duchenne muscular dystrophy (DMD), who are ambulatory and have a confirmed mutation in the *DMD* gene *[see Clinical Pharmacology (12.2), Clinical Studies (14)]*.

Limitations of Use:

ELEVIDYS is not recommended in patients with:

- Preexisting liver impairment (defined as gamma-glutamyl transferase [GGT] > 2 x upper limit of normal or total bilirubin > the upper limit of normal not due to Gilbert's syndrome) or active hepatic viral infection due to the high risk of acute serious liver injury and acute liver failure.
- Recent vaccination (within 4 weeks of treatment) due to immunogenicity and potential safety concerns.
- Active or recent (within 4 weeks) infections due to safety concerns.

2 DOSAGE AND ADMINISTRATION

For single-dose intravenous infusion only.

2.1 Critical Dosing Information

- Instruct patients to maintain proximity to an appropriate healthcare facility, as determined by the healthcare provider, for at least 2 months following ELEVIDYS infusion.
- Prior to ELEVIDYS infusion:
  - Select patients for treatment with ELEVIDYS with anti-AAVrh74 total binding antibody titers <1:400. An FDA-authorized test for the detection of anti-AAVrh74

total binding antibodies is not currently available. Currently available tests may vary in accuracy and design.
    - Avoid ELEVIDYS administration in patients with elevated anti-AAVrh74 total binding antibody titers (≥1:400) *[Clinical Pharmacology (12.6)]*.
    - Due to the increased risk of serious systemic immune response, postpone ELEVIDYS in patients with active or recent (within 4 weeks) infections *[see Warnings and Precautions (5.2)].*
    - Assess liver function (clinical examination and laboratory testing including aspartate aminotransferase (AST), alanine aminotransferase (ALT), gamma-glutamyl transferase (GGT), albumin, activated partial thromboplastin time (aPTT), international normalized ratio (INR), and total bilirubin) *[see Dosage and Administration (2.4), Warnings and Precautions (5.1), Use in Specific Populations (8.6)]*.
    - Obtain platelet count and troponin-I levels *[see Dosage and Administration (2.4), Warnings and Precautions (5.3)]*.
- Do not re-administer ELEVIDYS.

2.2 Recommended Dose

The recommended dose of ELEVIDYS is 1.33×10^{14} vector genomes per kilogram (vg/kg) of body weight (or 10 mL/kg body weight) for patients weighing less than 70 kg or 9.31×10^{15} vg total fixed dose for patients weighing 70 kg or greater.

For the number of vials required, refer to Table 10 *[see How Supplied/Storage and Handling (16.1)]*.

Calculate the dose as follows:

ELEVIDYS dose (in mL) = patient body weight (rounded to the nearest kilogram) x 10

The multiplication factor 10 represents the per kilogram dose (1.33×10^{14} vg/kg) divided by the amount of vector genome copies per mL of the ELEVIDYS suspension (1.33×10^{13} vg/mL).

Number of ELEVIDYS vials needed = ELEVIDYS dose (in mL) divided by 10.

Example: Calculation of volume needed for a 19.5 kg patient
19.5 kg rounded to the nearest kilogram = 20 kg
20 kg × 10 = 200 mL

Number of ELEVIDYS vials needed = 200 divided by 10, rounded to the nearest number of vials = 20 vials

Administer corticosteroids to reduce the risk of immune responses to the AAVrh74 vector after administration of ELEVIDYS *[see Clinical Pharmacology (12.6)]*. Start corticosteroids 1 day prior to ELEVIDYS infusion based on the schedule outlined in Table 1 below. Continue this regimen for a minimum of 60 days after the infusion, unless earlier tapering is clinically indicated.

Table 1: Recommended pre- and post-infusion oral corticosteroid dosing

Baseline corticosteroid dosing[a]	**Peri-ELEVIDYS infusion corticosteroid dose (prednisone equivalent)[b]**	**Recommended maximum total daily oral dose (prednisone**

		equivalent) b
Daily or intermittent dose	Start 1 day prior to infusion: 1 mg/kg/day (and continue baseline dose)	60 mg/day
High dose for 2 days per week	Start 1 day prior to infusion: 1 mg/kg/day taken on days without high-dose corticosteroid treatment (and continue baseline dose)	60 mg/day
Not on corticosteroids	Start 1 week prior to infusion: 1.5 mg/kg/day	60 mg/day

[a] Patient continues to receive this dose

[b] Corticosteroids other than prednisone and prednisolone have not been studied for use as a peri-ELEVIDYS infusion corticosteroid

Modify oral corticosteroid doses according to Table 2 for patients with liver function abnormalities (e.g., GGT >= 3 times baseline, total bilirubin > ULN) following ELEVIDYS infusion. Consider IV bolus corticosteroids instead of oral corticosteroids for GGT or bilirubin elevations that do not respond after 1 week of increased oral corticosteroids. Consult with a specialist experienced in immunosuppressive therapy for additional interventions as needed.

Obtain prompt consultation with a specialist (e.g., gastroenterologist or hepatologist) if acute serious liver injury or impending acute liver failure is suspected.

Taper the additional peri-ELEVIDYS corticosteroids for patients previously taking corticosteroids at baseline back to baseline dose over 2 weeks, or longer as needed. Taper the peri-ELEVIDYS corticosteroids for patients not previously taking corticosteroids at baseline back to no corticosteroids over 4 weeks, or longer as needed. Do not stop corticosteroids abruptly.

Table 2: Recommended oral corticosteroid regimen dose modification for liver function abnormalities following ELEVIDYS infusion[a]

Peri-ELEVIDYS infusion corticosteroid dosing	Modified oral corticosteroid dose following ELEVIDYS infusion (prednisone equivalent)[b c]	Recommended maximum total daily oral dose (prednisone equivalent)[b c]
Baseline + 1 mg/kg/day	Increase to 2 mg/kg/day (and continue baseline dose)	120 mg/day
Baseline + 1 mg/kg/day taken on days without high-dose corticosteroid treatment	Increase to 2 mg/kg/day taken on days without high-dose corticosteroid treatment (and continue baseline dose)	120 mg/day
1.5 mg/kg/day	Increase from 1.5 mg/kg/day to 2.5 mg/kg/day	120 mg/day

[a] GGT >= 3 times baseline and/or other clinically significant liver function abnormalities (e.g., total bilirubin > ULN) following infusion.

[b] Consider IV bolus corticosteroids instead of oral corticosteroids for GGT or bilirubin elevations that do not respond after 1 week of increased oral corticosteroids. Consult with a specialist experienced in immunosuppressive therapy for additional interventions as needed.

[C] Corticosteroids other than prednisone and prednisolone have not been studied for use as a peri-ELEVIDYS infusion corticosteroid.

2.3 Preparation

General precautions

- Prepare ELEVIDYS using aseptic technique.
- Verify the required dose of ELEVIDYS based on the patient's body weight.
- Confirm that the kit contains sufficient number of vials to prepare the ELEVIDYS infusion for the patient.
- Visually inspect parenteral drug products for particulate matter and discoloration prior to administration, whenever suspension and container permit. ELEVIDYS may contain white to off-white particles.

Recommended supplies and materials:

- 60 mL siliconized polypropylene syringes
- 21-gauge maximum or smaller stainless steel needles

Preparing ELEVIDYS infusion

1. Thaw ELEVIDYS before use.
    - When thawed in the refrigerator, ELEVIDYS vials are stable for up to 14 days in the refrigerator (2°C to 8°C [36º F to 46º F]) when stored in the upright position.
    - Frozen ELEVIDYS vials will thaw in approximately 2 hours when placed at room temperature (up to 25°C [77ºF]) when removed from original packaging.
    - Thawed ELEVIDYS is stable for up to 24 hours at room temperature (up to 25°C [77ºF]).
2. Inspect vials to ensure no ice crystals are present prior to preparation.
3. When thawed, swirl gently.
    - Do not shake.
    - Do not refreeze.
    - Do not place back in the refrigerator.
4. Visually inspect each vial of ELEVIDYS. ELEVIDYS is a clear, colorless liquid that may have some opalescence. ELEVIDYS may contain white to off-white particles.
    - Do not use if the suspension in the vials is cloudy or discolored.
5. Remove the plastic flip-off cap from the vials and disinfect the rubber stopper with a sterilizing agent (e.g., alcohol wipes).
6. Withdraw 10 mL of ELEVIDYS from each vial provided in the customized ELEVIDYS kit (refer to Table 10).
    - Do not use filter needles during preparation of ELEVIDYS.
    - Multiple syringes will be required to withdraw the required volume.
    - Remove air from the syringes and cap the syringes.
7. Maintain syringes at room temperature prior to and during administration.

2.4 Administration

Recommended supplies and materials:

- Syringe infusion pump
- 0.2-micron PES* in-line filter with a large surface area. To avoid the risk of occlusions, the use of smaller pediatric in-line filters (e.g., less than 10 cm^2 surface area) is not recommended.

- PVC* (non-DEHP*) IV infusion tubing, and polyurethane catheter

*PVC = Polyvinyl chloride, DEHP = Di(2-ethylhexyl) phthalate, PES = Polyether sulfone

Administer ELEVIDYS as a single-dose intravenous infusion through a peripheral venous catheter:

ELEVIDYS should be administered in a setting where treatment for infusion-related reactions is immediately available *[see Warnings and Precautions (5.4)]*. Do not infuse ELEVIDYS at a rate of 10 mL/kg/hour or faster.

Consider application of a topical anesthetic to the infusion site prior to administration of IV insertion.

Recommend inserting a back-up catheter.

1. Flush the intravenous access line with 0.9% Sodium Chloride Injection prior to the ELEVIDYS infusion at the same infusion rate.
2. Administer ELEVIDYS via intravenous infusion using a syringe infusion pump with an in-line 0.2-micron filter at a duration of approximately 1 to 2 hours, or longer at care team discretion, through a peripheral limb vein.
3. Infuse at a rate of less than 10 mL/kg/hour.
    - Do not administer ELEVIDYS as an intravenous push.
    - Do not infuse ELEVIDYS in the same intravenous access line with any other product.
    - Use ELEVIDYS within 12 hours after drawing into syringe. Discard the ELEVIDYS-containing syringe(s) if infusion of the drug has not been completed within the 12-hour timeframe.
4. In the event of an infusion-related reaction during administration *[see Warnings and Precautions (5.4)]:*
    - Slow or stop the infusion based on patient's clinical presentation.
    - Discontinue infusion for anaphylaxis.
    - Administer treatment as needed to manage infusion-related reaction.
    - ELEVIDYS infusion may be restarted at a lower rate after the infusion-related reaction has resolved at the discretion of the physician, based on severity of patient's clinical presentation.
    - If the ELEVIDYS infusion needs to be stopped and restarted, ELEVIDYS should be infused within 12 hours after drawing into the syringe *[see How Supplied/Storage and Handling (16.2)]*.
5. Flush the intravenous access line with 0.9% Sodium Chloride Injection after the ELEVIDYS infusion.
    - Discard unused ELEVIDYS *[see How Supplied/Storage and Handling (16.2)].*
    - Dispose of the needle and syringe *[see How Supplied/Storage and Handling (16.2)].*

Monitoring Post-ELEVIDYS Administration

- Assess liver function (clinical exam, AST, ALT, GGT, albumin, aPTT, INR, and total bilirubin) weekly for the first 3 months. Continue monitoring if clinically indicated, until results are unremarkable (e.g., normal clinical exam, GGT and total bilirubin levels return to near baseline levels) *[see Warnings and Precautions (5.1), Specific Populations (8.6)]*.
- Obtain platelet counts weekly for the first two weeks *[see Adverse Reactions (6.1)]*. Continue monitoring if clinically indicated.

- Measure troponin-I weekly for the first month *[see Warnings and Precautions (5.3)]*. Continue monitoring if clinically indicated, until results return to near baseline levels or stabilize.

3 DOSAGE FORMS AND STRENGTHS

ELEVIDYS is a preservative-free, sterile, clear, colorless liquid that may have some opalescence and may contain white to off-white particles.

ELEVIDYS is a suspension for intravenous infusion with a nominal concentration of 1.33×10^{13} vg/mL.

ELEVIDYS is provided in a customized kit containing ten to seventy 10 mL single-dose vials, with each kit constituting a dosage unit based on the patient's body weight *[see How Supplied/Storage and Handling (16.1)]*.

4 CONTRAINDICATIONS

ELEVIDYS is contraindicated in patients with any deletion in exon 8 and/or exon 9, including a deletion of any portion or the entirety of these exons, in the *DMD* gene *[see Warnings and Precautions (5.5)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Acute Serious Liver Injury and Acute Liver Failure

Acute serious liver injury marked by elevations of liver enzymes (e.g., GGT, ALT) and total bilirubin and acute liver failure, has occurred with ELEVIDYS. Onset of the liver injury typically begins within 8 weeks after administration of ELEVIDYS. In non-ambulatory patients treated with ELEVIDYS, acute liver failure with fatal outcome has occurred in the clinical and post-marketing settings.

Life-threatening mesenteric vein thrombosis, complicated by bowel ischemia and necrosis, and portal hypertension have been reported following acute liver injury associated with ELEVIDYS in a non-ambulatory patient *[see Adverse Reactions (6.2)]*.

Patients with preexisting liver impairment, chronic hepatic condition, or acute liver disease (e.g., acute hepatic viral infection) may be at higher risk of acute serious liver injury or acute liver failure. Postpone ELEVIDYS administration in patients with acute liver disease until resolved or controlled. Patients with hepatic impairment, acute liver disease, chronic hepatic condition or elevated GGT have not been studied in clinical trials with ELEVIDYS *[see Specific Populations (8.6)]*.

In clinical studies, liver function test increased (including increases in GGT, ALT, AST, or total bilirubin) was commonly reported typically within 8 weeks following ELEVIDYS infusion, with the majority of cases being asymptomatic *[see Adverse Reactions (6.1)]*. Most cases resolved spontaneously or with systemic corticosteroids and resolved without clinical sequelae within 2 months.

Prior to ELEVIDYS administration, perform liver enzyme test *[see Dosage and Administration (2.1)]*. Monitor liver function (clinical examination, AST, ALT, GGT, albumin, aPTT, INR, and total bilirubin) weekly for the first 3 months following ELEVIDYS infusion.

Continue monitoring if clinically indicated, until results are unremarkable (e.g., normal clinical exam, GGT and total bilirubin levels return to near baseline levels) *[see Dosage and Administration (2.4)]*.

Systemic corticosteroid treatment is recommended for patients before and after ELEVIDYS infusion *[see Dosage and Administration (2.2)]*. Adjust corticosteroid regimen when indicated *[see Dosage and Administration (2.2)]*. Obtain prompt consultation with a specialist (e.g., gastroenterologist or hepatologist) if acute serious liver injury or impending acute liver failure is suspected.

5.2 Serious Infections

Increased susceptibility to serious infections may occur due to concomitant administration of corticosteroid regimen and additional immunosuppressants, and ELEVIDYS. Serious respiratory infections, including with fatal outcomes, have occurred in patients taking immunosuppressant corticosteroids required for ELEVIDYS administration *[see Adverse Reactions (6.2)]*.

Monitor patients for signs and symptoms of infection before and after ELEVIDYS administration and treat appropriately. Administer immunizations according to best clinical practices and immunization guidelines prior to initiation of the corticosteroid regimen required before ELEVIDYS infusion *[see Drug Interactions (7)]*.

Avoid administration of ELEVIDYS to patients with active infections.

5.3 Myocarditis

Acute, serious, life-threatening myocarditis and troponin-I elevations have been observed within 24 hours to more than 1 year following ELEVIDYS infusion *[see Adverse Reactions (6.1)*].

If a patient experiences myocarditis, those with pre-existing left ventricle ejection fraction (LVEF) impairment may be at higher risk of adverse outcomes. Patients with moderate to severe LVEF impairment have not been studied in clinical trials with ELEVIDYS.

Monitor troponin-I before ELEVIDYS infusion and weekly for the first month following infusion *[see Dosage and Administration (2.4)]*. Continue monitoring if clinically indicated, until results return to near baseline levels or stabilize. More frequent monitoring may be warranted in the presence of cardiac symptoms, such as chest pain or shortness of breath.

Advise patients to contact a physician immediately if they experience cardiac symptoms.

5.4 Infusion-related Reactions

Infusion-related reactions, including hypersensitivity reactions and anaphylaxis, have occurred during or up to several hours following ELEVIDYS administration. Closely monitor patients during and for at least 3 hours after the end of infusion for signs and symptoms of infusion-related reactions including tachycardia, tachypnea, lip swelling, difficulty breathing, nasal flaring, urticaria, flushing, lip pruritus, rash, cheilitis, vomiting, nausea, rigors and pyrexia.

ELEVIDYS should be administered in a setting where treatment for infusion-related reactions is immediately available.

In the event of an infusion-related reaction, administration of ELEVIDYS may be slowed or stopped based on the severity of the patient's clinical presentation. Administer treatment as needed to manage infusion-related reactions based on the severity of patient's signs and symptoms. *[see Dosage and Administration (2.4)]*. If the infusion was stopped, ELEVIDYS infusion may be restarted at a lower rate once patient's symptoms have resolved, at the discretion of the physician. Discontinue infusion for anaphylaxis.

5.5 Immune-mediated Myositis

Immune-mediated myositis, including serious and life-threatening events, has occurred approximately 1 month following ELEVIDYS infusion *[see Adverse Reactions (6)*]. Signs and symptoms include severe muscle weakness, including dysphagia, dyspnea, dysphonia, and hypophonia.

These immune reactions may be due to a T-cell based response against specific regions of the micro-dystrophin transgenic protein. Severe to life-threatening immune-mediated myositis has been reported in patients with deletions including portions of exons 1-17 and/or exons 59-71 of the *DMD* gene. ELEVIDYS is contraindicated in patients with any deletion in exon 8 and/or exon 9, including a deletion of any portion or the entirety of these exons, in the *DMD* gene due to the increased risk for a severe immune-mediated myositis reaction *[see Contraindications (4)]*.

Regardless of genetic mutation, advise patients to contact a physician immediately if they experience any unexplained increased muscle pain, tenderness, or weakness, including dysphagia, dyspnea, dysphonia, or hypophonia as these may be symptoms of myositis. Consider additional immunomodulatory treatment based on patient's clinical presentation and medical history if these symptoms occur.

5.6 Pre-existing Immunity against AAVrh74

In AAV-vector based gene therapies, preexisting anti-AAV antibodies may impede transgene expression at desired therapeutic levels. Following treatment with ELEVIDYS all patients developed anti-AAVrh74 antibodies. Perform baseline testing for the presence of anti-AAVrh74 total binding antibodies prior to ELEVIDYS administration *[see Dosage and Administration (2.1)]*.

ELEVIDYS administration is not recommended in patients with elevated anti-AAVrh74 total binding antibody titers (≥1:400).

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety data described in this section reflect exposure to a one-time intravenous infusion of ELEVIDYS in 156 male patients with a confirmed mutation of the *DMD* gene in four clinical studies, including one completed open-label study, one ongoing open-label study, and two studies that included a double-blind, placebo-controlled period. Prior to ELEVIDYS infusion, patients in the ELEVIDYS treatment group had a mean age of 6.7 years (range: 3 to 20) and mean weight of 24.6 kg (range: 12.5 to 80.1). 144 patients

received the recommended dose of 1.33×10^{14} vg/kg, and 12 received a lower dose. Table 3 below presents adverse reactions from these four clinical studies.

The most common adverse reactions (incidence ≥5%) across all studies are summarized in Table 3.

Adverse reactions were typically seen within the first 2 weeks (nausea, vomiting, thrombocytopenia, pyrexia), the first month (myocarditis, troponin-I increased) or within the first 2 months (immune-mediated myositis, liver injury). Vomiting may occur as early as on the day of the infusion.

Table 3. Adverse reactions (Incidence ≥5%) following treatment with ELEVIDYS in Clinical Studies

Adverse reactions	ELEVIDYS (N=156) %
Vomiting	65
Nausea	43
Liver injury[a]	40
Pyrexia	28
Thrombocytopenia[b c]	8
Troponin-I increased [d]	8

[a] Includes: AST increased, ALT increased, GGT increased, GLDH increased, GLDH level abnormal, Hepatotoxicity, Hepatic enzyme increased, Hypertransaminasemia, Liver function test increased, Liver injury, Transaminases increased, Blood bilirubin increased

[b] Includes: Thrombocytopenia, Platelet count decreased

[c] Transient, mild, asymptomatic decrease in platelet counts

[d] Includes: Troponin I increased, Troponin increased, Troponin I abnormal

In clinical trials, immune-mediated myositis was observed in 2 of 6 patients with deletion mutations involving exon 8 and/or 9 in the *DMD* gene *[see Contraindications (4), and Warnings and Precautions (5.5)]*.

In the double-blind, placebo-controlled trial, Study 3 Part 1, patients 4 to 7 years of age (N=125) received either ELEVIDYS (N=63) at the recommended dose of 1.33×10^{14} vg/kg or placebo (N=62). Table 4 below presents the most frequent adverse reactions from Study 3 Part 1.

Table 4. Adverse reactions occurring in ELEVIDYS-treated patients and at least twice more frequently than with placebo in Study 3 Part 1

Adverse reactions	ELEVIDYS (N=63) %	Placebo (N=62) %
Vomiting	64	19
Nausea	40	13
Liver injury[a]	41	8
Pyrexia	32	24
Thrombocytopenia[bc]	3	0

[a] Includes: AST increased, ALT increased, GGT increased, GLDH increased, GLDH level abnormal, Hepatotoxicity, Hepatic enzyme increased, Hypertransaminasemia, Liver function test increased, Liver injury, Transaminases increased.

[b] Includes: platelet count decreased, thrombocytopenia
[c] Transient, mild, asymptomatic decrease in platelet counts

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of ELEVIDYS. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Hepatobiliary Disorders: Acute liver injury, acute liver failure, including fatal outcome and life-threatening mesenteric vein thrombosis *[see Warnings and Precautions (5.1)]*

Infections and Infestations: Bacterial and viral respiratory infections, including fatal outcome *[see Warnings and Precautions (5.2)]*

Immune System Disorders: Infusion-related reactions, including hypersensitivity reactions and anaphylaxis, have occurred during or up to several hours following ELEVIDYS administration *[see Warnings and Precautions (5.4)]*.

Musculoskeletal and connective tissue disorders: Immune-mediated myositis *[see Warnings and Precautions (5.5)].*

7 DRUG INTERACTIONS

Prior to initiating the corticosteroid regimen required before ELEVIDYS administration, consider the patient's vaccination status. Patients should, if possible, be brought up to date with all immunizations in agreement with current immunization guidelines. Vaccinations should be completed at least 4 weeks prior to initiation of the corticosteroid regimen.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

ELEVIDYS is not intended for use in pregnant women.

In the U.S. general population, the estimated background risks of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

8.2 Lactation

Risk Summary

There is no information available on the presence of ELEVIDYS in human milk, the effects on the breastfed infant, or the effects on milk production.

8.4 Pediatric Use

The safety and effectiveness of ELEVIDYS for the treatment of Duchenne muscular dystrophy has been established in pediatric patients at least 4 years of age with a

confirmed mutation in the *DMD* gene. The use of ELEVIDYS in pediatric patients was supported by evidence from three adequate and well controlled clinical studies which included 144 pediatric patients aged 4 years of age and older *[see Adverse Reactions (6), Clinical Pharmacology (12.2), Clinical Studies (14)]*.

8.5 Geriatric Use

The safety and efficacy of ELEVIDYS in geriatric patients with DMD have not been studied.

8.6 Hepatic Impairment

The safety and efficacy of ELEVIDYS in patients with hepatic impairment or elevated GGT have not been studied.

Postpone ELEVIDYS administration in patients with acute liver disease until resolved or controlled. Treatment with ELEVIDYS should be carefully considered in patients with preexisting liver impairment or chronic hepatic viral infection. These patients may be at increased risk of acute serious liver injury or acute liver failure *[see Warnings and Precautions (5.1)]*.

In clinical trials, liver function test increase was commonly reported in patients following ELEVIDYS infusion *[see Warnings and Precautions (5.1), Adverse Reactions (6.1)]*.

11 DESCRIPTION

ELEVIDYS (delandistrogene moxeparvovec-rokl) is a recombinant gene therapy designed to deliver the gene encoding the ELEVIDYS micro-dystrophin protein. ELEVIDYS is a non-replicating, recombinant, adeno-associated virus serotype rh74 (AAVrh74) based vector containing the ELEVIDYS micro-dystrophin transgene under the control of the MHCK7 promoter. The genome within the ELEVIDYS AAVrh74 vector contains no viral genes and consequently is incapable of replication or reversion to a replicating form. The micro-dystrophin protein expressed by ELEVIDYS is a shortened version (138 kDa, compared to 427 kDa size of dystrophin expressed in normal muscle cells) that contains selected domains of dystrophin expressed in normal muscle cells.

ELEVIDYS is a preservative-free, sterile, clear, colorless liquid that may have some opalescence and may contain white to off-white particles. ELEVIDYS is a suspension for intravenous infusion with a nominal concentration of 1.33×10^{13} vg/mL and supplied in a single-dose 10 mL vial. Each vial contains an extractable volume of 10 mL and the following excipients: 200mM sodium chloride, 13 mM tromethamine HCl, 7 mM tromethamine, 1mM magnesium chloride, 0.001% poloxamer 188, with a pH of 8.0 ± 0.3.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

ELEVIDYS is the recombinant gene therapy product that is comprised of a non-replicating, recombinant, adeno-associated virus (AAV) serotype rh74 (AAVrh74) capsid and a single-stranded DNA expression cassette flanked by inverted terminal repeats (ITRs) derived from AAV2. The cassette contains: 1) an MHCK7 gene regulatory

component comprising a creatine kinase 7 promoter and an α-myosin heavy chain enhancer, and 2) the DNA transgene encoding the engineered micro-dystrophin protein.

Vector/Capsid: Clinical and nonclinical studies have demonstrated AAVrh74 serotype transduction in skeletal muscle cells. Additionally, in nonclinical studies, AAVrh74 serotype transduction has been demonstrated in cardiac and diaphragm muscle cells.

Promoter: The MHCK7 promoter/enhancer drives transgene expression and has been shown in animal models to drive transgenic micro-dystrophin protein expression predominantly in skeletal muscle (including diaphragm) and cardiac muscle. In clinical studies, muscle biopsy analyses have confirmed micro-dystrophin expression in skeletal muscle.

Transgene: DMD is caused by a mutation in the *DMD* gene resulting in lack of functional dystrophin protein. ELEVIDYS carries a transgene encoding a micro-dystrophin protein consisting of selected domains of dystrophin expressed in normal muscle cells.

ELEVIDYS micro-dystrophin has been demonstrated to localize to the sarcolemma.

12.2 Pharmacodynamics

In 92 patients who received ELEVIDYS in clinical studies, micro-dystrophin protein expression from muscle biopsies (gastrocnemius or biceps brachii) was quantified by western blot and localized by immunofluorescence staining (fiber intensity and percentage micro-dystrophin).

Micro-dystrophin expression (expressed as change from baseline) in ELEVIDYS-treated patients as measured by western blot was the primary objective of Study 1 and Study 2, and a key secondary objective for Study 3. Muscle biopsies were obtained at baseline prior to ELEVIDYS infusion and at Week 12 after ELEVIDYS infusion in all patients. The absolute quantity of micro-dystrophin was measured by western blot assay, adjusted by muscle content and expressed as a percent of control (levels of wild-type dystrophin in patients without DMD or Becker muscular dystrophy) in muscle biopsy samples. Study 1 and 2 results of patients receiving 1.33×10^{14} vg/kg ELEVIDYS are presented in Table 5.

Table 5. Micro-Dystrophin Expression in Study 1 and Study 2 at Week 12 from Baseline (Western Blot Assay)[abc]

Western blot (% of micro-dystrophin compared to control)	Study 1 Part 1 (n=6)	Study 1 Part 2 (n=21)	Study 2 Ambulatory (n=40)
Mean change from baseline (SD)	43.4 (48.6)	40.7 (32.3)	51.0 (47)
Median change from baseline (Min, Max)	24.3 (1.6, 116.3)	40.8 (0.0, 92.0)	46.9 (1.9, 197.3)

[a] All patients received 1.33×10^{14} vg/kg, as measured by ddPCR

[b] Change from baseline was statistically significant

[c] Adjusted for muscle content. Control was level of wild-type (normal) dystrophin in normal muscle.

In Study 3 Part 1, muscle biopsies were obtained at Week 12 in 31 patients. For the ELEVIDYS-treated patients, the mean micro-dystrophin expression at Week 12 was 34.3% (N=17, SD: 41.0%), compared to placebo patients of 0% (N=14, SD: 0%).

Assessment of micro-dystrophin levels can be meaningfully influenced by differences in sample processing, analytical technique, reference materials, and quantitation methodologies. Therefore, valid comparisons of micro-dystrophin measurements obtained from different assays cannot be made.

12.3 Pharmacokinetics

Vector Distribution and Vector Shedding

Nonclinical Data

Biodistribution of ELEVIDYS was evaluated in tissue samples collected from healthy mice and DMD^{mdx} mice following intravenous administration in toxicology studies. At 12 weeks following ELEVIDYS administration at dose levels of 1.33×10^{14} to 4.02×10^{14} vg/kg, vector DNA was detected in all major organs with the highest quantities detected in the liver, followed by lower levels in the heart, adrenal glands, skeletal muscle, and aorta. ELEVIDYS was also detected at low levels in the spinal cord, sciatic nerve and gonads (testis). Protein expression of micro-dystrophin was highest in cardiac tissue, exceeding physiologic dystrophin expression levels in healthy mice, with lower levels in the skeletal muscle and diaphragm. In some studies, micro-dystrophin was also detected at low levels in the liver.

Clinical Data

Following IV administration, ELEVIDYS vector genome undergoes distribution via systemic circulation and distributes into target muscle tissues followed by elimination in the urine and feces. ELEVIDYS biodistribution and tissue transduction are detected in the target muscle tissue groups and quantified in the gastrocnemius or biceps femoris biopsies obtained from patients with mutations in the *DMD* gene. Evaluation of ELEVIDYS vector genome exposure in clinical muscle biopsies at Week 12 post-dose expressed as copies per nucleus revealed ELEVIDYS drug distribution and transduction with a mean change from baseline of 2.91 and 3.44 copies per nucleus at the recommended dose of 1.33×10^{14} vg/kg for Study 1 and Study 2 Cohort 1, respectively.

In Study 2 Cohorts 1-3, the biodistribution and vector shedding of ELEVIDYS in the serum and excreta were quantified, respectively. The mean maximum concentration (C_{max}) in the serum was 0.0055×10^{13} copies/mL and 2.78×10^{6} copies/mL in the urine, 7.86×10^{7} copies/mL in the saliva, and 4.87×10^{7} copies/µg in the feces. The median time to achieve maximum concentration (T_{max}) was 5.8 hours post-dose in the serum, followed by 6.7 hours, 6.5 hours and 13 days post-dose in the saliva, urine, and feces, respectively. The median time to achieve first below limit of quantification (BLOQ) sample followed by 2 consecutive BLOQ samples was 55 days post-dose for serum. The median time to achieve complete elimination as the first below limit of detection (BLOD) sample followed by 2 consecutive BLOD samples were 49.8 days, 78 days and 162 days post-dose for saliva, urine and feces, respectively. The estimated elimination half-life of ELEVIDYS vector genome in the serum is approximately 12 hours, and the majority of the drug is expected to be cleared from the serum by 1-week post-dose. In the excreta, the estimated elimination half-life of ELEVIDYS vector genome is approximately 40 hours, 55 hours, and 60 hours in the urine, feces, and saliva, respectively. As an AAV-based gene therapy that consists of a protein capsid containing the transgene DNA genome of interest, ELEVIDYS capsid proteins are broken down through proteasomal degradation following AAV entry into target cells. As such, ELEVIDYS is not likely to exhibit the drug-drug interaction potential mediated by known drug metabolizing enzymes (cytochrome

P450-based) and drug transporters.

12.6 Immunogenicity

The observed incidence of anti-AAVrh74 antibodies is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of anti-AAVrh74 antibodies in the studies described below with the incidence of anti-AAVrh74 antibodies in other studies.

In ELEVIDYS clinical studies, patients were required to have baseline anti-AAVrh74 total binding antibodies of <1:400, measured using an investigational total binding antibody enzyme-linked immunosorbent assay (ELISA), and only patients with baseline anti-AAVrh74 total binding antibodies <1:400 were enrolled in those studies.

Across clinical studies evaluating a total of 156 patients, elevated anti-AAVrh74 total binding antibodies titers were observed in all patients following a one-time ELEVIDYS infusion. Anti-AAVrh74 total binding antibody titers reached at least 1:3200 in every patient, and the maximum titers exceeded 1:26,214,400 in certain patients. The safety of re-administration of ELEVIDYS or any other AAVrh74 vector-based gene therapy in the presence of high anti-AAVrh74 total binding antibody titer has not been evaluated in humans *[see Warnings and Precautions (5.6)]*.

There is insufficient data to assess whether the observed anti-AAVrh74 antibodies titers have clinically significant effect on pharmacokinetics, pharmacodynamics, safety, and efficacy of ELEVIDYS.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No animal studies have been performed to evaluate the effects of ELEVIDYS on carcinogenicity, mutagenesis, or impairment of fertility.

14 CLINICAL STUDIES

The efficacy of ELEVIDYS was evaluated in two double-blind, placebo-controlled studies (Study 1 [NCT 03769116] and Study 3 [NCT 05096221]) and one open-label study (Study 2 [NCT 04626674]) in which a total of 214 male patients with a confirmed disease-causing mutation in the *DMD* gene were dosed.

Study 1

Study 1 is a completed multi-center study including:

- Part 1: a 48-week, randomized, double-blind, placebo-controlled period
- Part 2: a 48-week period that began following completion of Part 1. Patients who received placebo during Part 1 were treated with ELEVIDYS, and patients treated with ELEVIDYS during Part 1 received placebo.

The study population consisted of male ambulatory DMD patients (N=41) aged 4 through 7 years with either a confirmed frameshift mutation, or a premature stop codon mutation between exons 18 to 58 in the *DMD* gene.

Patients were randomized 1:1 to receive either ELEVIDYS (N=20) or placebo (N=21), as

a single intravenous infusion via a peripheral limb. Randomization was stratified by age (i.e., aged 4 to 5 years vs. aged 6 to 7 years). In the 4 through 5-year-old subgroup, the mean age, mean weight and mean NSAA total score (range) for the ELEVIDYS-treated patients (n=8) were 4.98 years, 20.1 kg and 20.1 (17-23), and for the placebo patients (n=8) were 5.15 years, 19.8 kg and 20.4 (15-24). In the ELEVIDYS group, eight patients received 1.33×10^{14} vg/kg of ELEVIDYS, and 12 patients received lower doses. Key demographic and baseline characteristics are presented in Table 6.

Table 6: Key Demographic and Baseline Characteristics (Study 1 Part 1)

Characteristic	**All (n=41)**	**ELEVIDYS (n=20)**	**Placebo (n=21)**
Race (%) Asian/Black or African American/White/Other	12/0/73/15	20/0/65/15	5/0/81/14
Ethnicity (%) Hispanic or Latino/ Other	12/88	5/95	19/81
Mean age [range] (years)	6.3 [4.3 to 7.9]	6.3 [4.5 to 7.9]	6.2 [4.3 to 7.9]
Mean weight [range] (kg)	22.4 [15.0 to 34.5]	23.3 [18.0 to 34.5]	21.6 [15.0 to 30.0]
Mean NSAA total score [range]	21.2 [13 to 29]	19.8 [13 to 26]	22.6 [15 to 29]
Mean time to rise from floor [range] (seconds)	4.3 [2.7 to 10.4]	5.1 [3.2 to 10.4]	3.6 [2.7 to 4.8]

All patients were on a stable dose of corticosteroids for DMD for at least 12 weeks prior to ELEVIDYS infusion. All randomized patients had baseline anti-AAVrh74 antibody titers <1:400 as determined by an investigational total binding antibody ELISA.

One day prior to treatment with ELEVIDYS or placebo, the patient's background dose of corticosteroid for DMD was increased to at least 1 mg/kg of a corticosteroid (prednisone equivalent) daily and was continued at this level for at least 60 days after the infusion, unless earlier tapering was clinically indicated.

The efficacy outcomes of Study 1 were to evaluate expression of micro-dystrophin in skeletal muscle, and to evaluate the effect of ELEVIDYS on the North Star Ambulatory Assessment (NSAA) total score.

Results of micro-dystrophin measured by western blot are presented in Table 5 *[see Clinical Pharmacology (12.2)]*.

The change in NSAA total score was assessed from baseline to Week 48 after infusion of ELEVIDYS or placebo. The difference between the ELEVIDYS and placebo groups was not statistically significant (p=0.37). The least squares (LS) mean changes in NSAA total score from baseline to Week 48 was 1.7 (standard error [SE]: 0.6) points for the ELEVIDYS group and 0.9 (SE: 0.6) points for the placebo group.

Exploratory subgroup analyses showed that for patients aged 4 through 5 years, the LS

mean changes (SE) in NSAA total score from baseline to Week 48 were 4.3 (0.7) points for the ELEVIDYS group, and 1.9 (0.7) points for the placebo group, a numerical advantage for ELEVIDYS. For patients aged 6 through 7 years, the LS mean changes (SE) in NSAA total score from baseline to Week 48 were -0.2 (0.7) points for the ELEVIDYS group and 0.5 (0.7) points for the placebo group, a numerical disadvantage for ELEVIDYS.

Study 2

Study 2 is an ongoing, open-label, multi-center study which includes 5 cohorts of 48 male DMD patients.

Patients in cohorts 1, 2 and 3 have a confirmed frameshift, splice site or premature stop codon mutation anywhere in the *DMD* gene, while patients in cohort 4 included patients with mutations in the *DMD* gene starting at or after exon 18. All patients in cohort 5 had mutations that partially or fully overlap with exons 1-17 in the *DMD* gene. Patients received corticosteroids for DMD before infusion according to Table 1 *[see Dosage and Administration (2.2)]*. All patients had baseline anti-AAVrh74 antibodies titers ≤1:400 as determined by the investigational total binding antibody ELISA. Patients received a single intravenous infusion of 1.33×10^{14} vg/kg ELEVIDYS if they weighed less than 70 kg or 9.31×10^{15} vg/kg total fixed dose if they weighed 70 kg or greater.

Cohorts 1, 2, 4 and 5a enrolled 40 ambulatory patients 3 to 12 years of age, with weights ranging from 12.5 to 50.5 kg, baseline mean NSAA total score of 20.3 (11 to 30), and mean time to rise from floor of 4.7 seconds (2.4 to 9.7). Cohorts 3 and 5b include 8 non-ambulatory patients 10 to 20 years of age, with weights ranging from 36.1 to 80.1 kg. Overall key demographics and key baseline characteristics by Cohort are presented in Table 7.

Table 7: Key Demographic and Baseline Characteristics for Study 2

Characteristics	**All (n=48)**	**Cohort 1 (n=20)**	**Cohort 2 (n=7)**	**Cohort 3[a] (n=6)**	**Cohort 4 (n=7)**	**Cohort 5a (n=6)**	**Cohort 5b[a] (n=2)**
Race (%) Asian/Black or African American/White/Other	8/6/77/8	5/5/75/15	14/0/71/14	0/0/100/0	14/0/86/0	0/33/67/0	50/0/50/0
Ethnicity (%) Hispanic or Latino/ Not Hispanic or Latino	15/85	25/75	14/86	0/100	14/86	0/100	0/100
Mean age [range] (years)	7.7 [3.2 to 20.2]	5.8 [4.4 to 7.9]	10.1 [8.0 to 12.1]	15.3 [9.9 to 20.2]	3.5 [3.2 to 3.9]	6.7 [4.7 to 8.6]	13.4 [12.3 to 14.6]
Mean weight [range] (kg)	30.1 [12.5 to 80.1]	21.2 [15.2 to 33.1]	37.1 [28.0 to 50.5]	59.9 [36.1 to 80.1]	15.2 [12.5 to 16.5]	32.1 [19.1 to 47.4]	51.2 [43.4 to 59.0]
Mean NSAA total score [range]	20.3 [11 to 30]	22.1 [18 to 26]	20.7 [17 to 26]	N/A	12.9 [11 to 17]	22.5 [18 to 30]	N/A
Mean time to rise from floor [range] (seconds)	4.7 [2.4 to 9.7]	4.2 [2.4 to 8.2]	5.9 [3.8 to 9.7]	N/A	5.2 [3.8 to 6.7]	4.6 [2.5 to 7.7]	N/A

Mean Performance of Upper Limb v. 2.0 score [range]	30.7 [18 to 42]	NA	38.9 [33 to 42]	22.2 [18 to 31]	NA	NA	27.5 [21 to 34]

[a] NSAA and Time to rise from floor were not evaluated in non-ambulatory patients

The efficacy outcome measure of the study was to evaluate the effect of micro-dystrophin expression as measured by western blot. Results are presented in Table 5 *[see Clinical Pharmacology (12.2)]*.

Study 3

Study 3 is a multi-center, randomized, double-blind, placebo-controlled study in which 125 ambulatory male patients aged 4 through 7 years, with a confirmed frameshift, splice site, premature stop codon, or other disease-causing mutation in the *DMD* gene starting at or after exon 18, were dosed. Patients with exon 45 (inclusive), or in-frame deletions, in-frame duplications, and variants of uncertain significance ("VUS"), were excluded. Patients received corticosteroids for DMD before infusion according to Table 1 *[see Dosage and Administration (2.2)]*. All patients had baseline anti-AAVrh74 antibodies titers <1:400 as determined by the investigational total binding antibody ELISA and received a single intravenous infusion of 1.33×10^{14} vg/kg ELEVIDYS. Key demographic and baseline characteristics are presented in Table 8.

The efficacy outcome measure of the study was to evaluate the effect of ELEVIDYS on physical function as assessed by the NSAA total score. Key secondary outcome measures were to evaluate expression of micro-dystrophin in skeletal muscle, time to rise from floor, and time of 10-meter walk/run. Additional efficacy outcome measures included time of 100-meter walk/run, and time to ascend 4 steps. Results of micro-dystrophin measured by western blot are presented in Table 5 *[see Clinical Pharmacology (12.2)]*.

Table 8: Key Demographic and Baseline Characteristics for Study 3

Characteristic	**ELEVIDYS (n=63)**	**Placebo (n=62)**
Race (%) Asian/Black or African American/ White/Multiple/Other/Not Reported	13/0/78/2/3/5	18/3/74/0/2/3
Ethnicity (%) Hispanic or Latino/Not Hispanic or Latino/ Not Reported/Unknown	24/75/0/2	13/86/2/0
Mean age [range] (years)	6.0 [4.1 to 7.9]	6.1 [4.0 to 7.9]
Mean weight [range] (kg)	21.3 [13.5 to 38.5]	22.4 [14.4 to 41.6]
Mean NSAA total score [range]	23.10 [14 to 32]	22.82 [15.5 to 30]
Mean time to rise from floor [range] (seconds)	3.52 [1.9 to 5.8]	3.60 [2.3 to 5]

Mean time of 10-meter walk/run [range] (seconds)	4.82 [3.2 to 6.9]	4.92 [3.7 to 7]
Mean time of 100-meter walk/run [range] (seconds)	60.67 [38.0 to 129.2]	63.01 [38.7 to 118.1]
Mean time to ascend 4 steps [range] (seconds)	3.17 [1.6 to 7.1]	3.37 [1.5 to 7.1]

The change in NSAA total score was assessed from baseline to Week 52 after infusion of ELEVIDYS or placebo. The difference between the ELEVIDYS (n=63) and placebo groups (n=61) was not statistically significant (p=0.24). The least squares (LS) mean changes in NSAA total score from baseline to Week 52 was 2.57 (95% confidence interval [CI]: 1.80, 3.34) points for the ELEVIDYS group and 1.92 (95% CI: 1.14, 2.70) points for the placebo group, with a LS mean difference from placebo of 0.65 (95% CI: -0.45, 1.74). Changes of clinical relevance were noted in three secondary efficacy endpoints, including time to rise from the floor, 10-meter walk/run and time to ascend 4 steps.

Table 9: Change from Baseline to Week 52 of Timed Function Tests in Study 3 Part 1

	ELEVIDYS	**Placebo**	**LS Mean Difference from placebo (95% CI)**
Time to rise from the floor (seconds)	n=63	n=61	-
LS mean Change (95% CI)	-0.27 (-0.56, 0.02)	0.37 (0.08, 0.67)	-0.64 (-1.06, -0.23)
Time of 10-meter walk/run (seconds)	n=63	n=61	-
LS mean Change (95% CI)	-0.34 (-0.55, -0.14)	0.08 (-0.13, 0.29)	-0.42 (-0.71, -0.13)
Time of 100-meter walk/run (seconds)	n=59	n=57	-
LS mean Change (95% CI)	-6.57 (-10.05, -3.09)	-3.28 (-6.86, 0.29)	-3.29 (-8.28, 1.70)
Time to ascend 4 steps (seconds)	n=62	n=60	-
LS mean Change (95% CI)	-0.44 (-0.69, -0.20)	-0.08 (-0.33, 0.17)	-0.36 (-0.71, -0.01)

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

ELEVIDYS is shipped frozen (≤ -60ºC [-76ºF]) in 10 mL vials.

ELEVIDYS is supplied as a customized kit to meet dosing requirements for each patient *[see Dosage and Administration (2.2)]*. Each kit contains:

- Ten (10) to seventy (70) single-dose vials of ELEVIDYS
- One alcohol wipe per vial

Each ELEVIDYS pack may contain a maximum of two different drug product lots.

The total number of vials in each kit corresponds to the dosing requirement for the individual patient, based on the patient's body weight, and is specified on the package *[see Dosage and Administration (2.2)]*. Each kit includes a specified number of ELEVIDYS vials (with a minimum of 10 vials for a patient with 10.0 – 10.4 kg body weight range, and a maximum of 70 vials for a patient with body weight of 69.5 kg and above).

Kit sizes and National Drug Codes (NDC) are provided in Table 10.

Table 10: ELEVIDYS Multi-vial Kits

Patient Weight (kg)	Total Vials per Kit	Total Dose Volume per Kit (mL)	NDC Number
10.0 – 10.4	10	100	60923-501-10
10.5 – 11.4	11	110	60923-502-11
11.5 – 12.4	12	120	60923-503-12
12.5 – 13.4	13	130	60923-504-13
13.5 – 14.4	14	140	60923-505-14
14.5 – 15.4	15	150	60923-506-15
15.5 – 16.4	16	160	60923-507-16
16.5 – 17.4	17	170	60923-508-17
17.5 – 18.4	18	180	60923-509-18
18.5 – 19.4	19	190	60923-510-19
19.5 – 20.4	20	200	60923-511-20
20.5 – 21.4	21	210	60923-512-21
21.5 – 22.4	22	220	60923-513-22
22.5 – 23.4	23	230	60923-514-23
23.5 – 24.4	24	240	60923-515-24
24.5 – 25.4	25	250	60923-516-25
25.5 – 26.4	26	260	60923-517-26
26.5 – 27.4	27	270	60923-518-27
27.5 – 28.4	28	280	60923-519-28
28.5 – 29.4	29	290	60923-520-29
29.5 – 30.4	30	300	60923-521-30
30.5 – 31.4	31	310	60923-522-31
31.5 – 32.4	32	320	60923-523-32
32.5 – 33.4	33	330	60923-524-33
33.5 – 34.4	34	340	60923-525-34
34.5 – 35.4	35	350	60923-526-35
35.5 – 36.4	36	360	60923-527-36
36.5 – 37.4	37	370	60923-528-37
37.5 – 38.4	38	380	60923-529-38

38.5 – 39.4	39	390	60923-530-39
39.5 – 40.4	40	400	60923-531-40
40.5 – 41.4	41	410	60923-532-41
41.5 – 42.4	42	420	60923-533-42
42.5 – 43.4	43	430	60923-534-43
43.5 – 44.4	44	440	60923-535-44
44.5 – 45.4	45	450	60923-536-45
45.5 – 46.4	46	460	60923-537-46
46.5 – 47.4	47	470	60923-538-47
47.5 – 48.4	48	480	60923-539-48
48.5 – 49.4	49	490	60923-540-49
49.5 – 50.4	50	500	60923-541-50
50.5 – 51.4	51	510	60923-542-51
51.5 – 52.4	52	520	60923-543-52
52.5 – 53.4	53	530	60923-544-53
53.5 – 54.4	54	540	60923-545-54
54.5 – 55.4	55	550	60923-546-55
55.5 – 56.4	56	560	60923-547-56
56.5 – 57.4	57	570	60923-548-57
57.5 – 58.4	58	580	60923-549-58
58.5 – 59.4	59	590	60923-550-59
59.5 – 60.4	60	600	60923-551-60
60.5 – 61.4	61	610	60923-552-61
61.5 – 62.4	62	620	60923-553-62
62.5 – 63.4	63	630	60923-554-63
63.5 – 64.4	64	640	60923-555-64
64.5 – 65.4	65	650	60923-556-65
65.5 – 66.4	66	660	60923-557-66
66.5 – 67.4	67	670	60923-558-67
67.5 – 68.4	68	680	60923-559-68
68.5 – 69.4	69	690	60923-560-69
69.5 and above	70	700	60923-561-70

A 10 mL single-dose vial carton for ELEVIDYS (NDC 60923-562-01) is not sold individually.

16.2 Storage and Handling

- ELEVIDYS is shipped and delivered at ≤ −60ºC [−76ºF].
- ELEVIDYS can be refrigerated for up to 14 days when stored at 2°C to 8°C (36º F to 46º F) in the upright position.
- Do not refreeze.
- Do not shake.
- Do not place back in the refrigerator once brought to room temperature.
- Follow local guidelines on handling of biological waste.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved Medication Guide.

Provide a copy of the Medication Guide and review the contents with the patient.

Inform patients or caregivers that:

- ELEVIDYS can increase certain liver enzyme levels and cause acute serious liver injury or acute liver failure, and death. Management of acute serious liver injury may require hospitalization. Patients will receive oral corticosteroid medication before and after infusion with ELEVIDYS. Weekly blood tests will be required to monitor liver enzyme levels for 3 months after treatment. Contact a healthcare provider immediately if the patient's skin and/or whites of the eyes appear yellowish, if the patient misses a dose of corticosteroid or vomits it up, or if the patient experiences a change in mental status *[see Warnings and Precautions (5.1)]*.
- Due to the concomitant administration of corticosteroids, an infection (e.g., cold, flu, gastroenteritis, otitis media, bronchiolitis, pneumonia, etc.) before or after ELEVIDYS infusion could lead to more serious complications, including death. Contact a healthcare provider immediately if symptoms suggestive of infection are observed (e.g., coughing, wheezing, sneezing, runny nose, sore throat, or fever) *[see Warnings and Precautions (5.2)]*.
- Myocarditis (inflammation of the heart) has been observed within days to more than a year following ELEVIDYS infusion. Weekly monitoring of troponin-I for the first month after treatment is required. Contact a healthcare provider immediately if the patient begins to experience chest pain and/or shortness of breath *[see Warnings and Precautions (5.3)]*.
- Infusion-related reactions including hypersensitivity and anaphylaxis have occurred during and after ELEVIDYS infusion. Possible symptoms of infusion-related reactions are fast heart rate, fast breathing, swollen lips, being short of breath, nostrils widening, hives, red and blotchy skin, itchy or inflamed lips, rash, vomiting, nausea, chills and fever. Contact a healthcare provider immediately if the patient experiences such a reaction *[see Warnings and Precautions (5.4)].*
- Immune-mediated myositis (an immune response affecting muscles) was observed in some patients following ELEVIDYS infusion. Contact a physician immediately if the patient experiences any unexplained increased muscle pain, tenderness, or weakness, including difficulty swallowing, difficulty breathing or difficulty speaking, as these may be symptoms of myositis *[see Warnings and Precautions (5.5)]*.
- Patient's immunizations should be up to date with current immunization guidelines prior to initiation of the corticosteroid regimen required before ELEVIDYS infusion. Vaccinations should be completed at least 4 weeks prior to initiation of the corticosteroid regimen *[see Drug Interactions (7)]*.
- Vector shedding of ELEVIDYS occurs primarily through body waste. Practice proper hand hygiene, such as hand washing, when coming into direct contact with patient body waste. Place potentially contaminated materials that may have the patient's bodily fluids/waste in a sealable bag and dispose into regular trash. These precautions should be followed for one month after ELEVIDYS infusion.

Manufactured for: Sarepta Therapeutics, Inc.
Cambridge, MA 02142 USA
U.S. license number 2308

Elevidys
delandistrogene
moxeparvovec-rokl
suspension for intracenous infusion

MEDICATION GUIDE
ELEVIDYS (Ah-LEV-ah-dis)
(delandistrogene moxeparvovec-rokl)
suspension, for intravenous use

What is the most important information that you/your child should know about ELEVIDYS?

1. **Rapid serious liver injury and rapid liver failure. ELEVIDYS can increase certain liver lab test levels and cause rapid serious liver injury, rapid liver failure, and death.** Complication of blood clots in the blood vessel in the abdomen that helps carry blood from the intestines to the liver has happened. Patients with preexisting liver problems may be at higher risk.
   - You/your child will receive oral corticosteroid medication before and after ELEVIDYS infusion and will need weekly blood tests to monitor liver function for 3 months or longer after treatment.
   - For at least 2 months following ELEVIDYS infusion, stay close to a healthcare facility that your/your child's doctor recommends.
   - Contact your/your child's doctor immediately if your/your child's skin and/or whites of the eyes appear yellowish or if your/your child misses a dose of corticosteroid or vomits it up.
2. **Serious Infection.** Because you/your child will be taking corticosteroids as part of ELEVIDYS treatment, this may lower the ability of your/your child's immune system to fight infections and make it easier to get an infection. Getting an infection (like a cold, flu, stomach flu, ear infection, chest infection) before or after ELEVIDYS infusion could lead to more serious health problems, including death. Contact your/your child's doctor right away if you notice any signs of infection such as:

   - coughing
   - wheezing
   - sneezing
   - runny nose
   - sore throat
   - fever

   - Vaccinations should be completed at least 4 weeks before starting the corticosteroids that are part of the ELEVIDYS treatment.
   - **ELEVIDYS should not be given if you have/your child has an infection.**
3. **Inflammation of the heart muscle (Myocarditis).** Serious and life-threatening inflammation of the heart muscle has happened following ELEVIDYS infusion. In individuals who develop inflammation of the heart muscle after receiving ELEVIDYS, they may be at a higher risk of serious complications if they already had a heart condition that has affected how well the heart pumps.

   You/Your child will need weekly blood tests for a heart protein that can detect damage to muscle cells in the heart (troponin-I) for the first month after ELEVIDYS infusion. Contact your/your child's doctor right away if you notice:

- chest pain
- trouble breathing or shortness of breath

4. **Infusion-related reactions.** Reactions from the infusion, including serious allergic reactions, may happen during or after ELEVIDYS infusion. Contact your/your child's doctor right away if you notice:

- fast heart rate
- fast breathing
- swollen lips
- shortness of breath
- nostrils widening
- hives
- red and blotchy skin
- itchy or inflamed lips
- rash
- vomiting
- nausea
- chills
- fever

5. **Immune response affecting muscles (Immune-mediated myositis). Immune response affecting muscles, including serious and life-threatening reactions, has happened in patients about 1 month after receiving ELEVIDYS infusion.** Contact your/your child's doctor right away if you notice:

- Unexplained increased muscle pain
- Tenderness
- Weakness, including trouble swallowing, breathing or speaking

See **"What are the possible side effects of ELEVIDYS?"** for more information about side effects.

What is ELEVIDYS?

ELEVIDYS is a prescription gene therapy used to treat ambulatory individuals at least 4 years old with Duchenne muscular dystrophy (DMD) who have a confirmed mutation in the *DMD* gene.

ELEVIDYS is not recommended for individuals with:

- Preexisting liver problems or liver infection because of the high risk of rapid serious liver injury and rapid liver failure
- Recent vaccination (within 4 weeks of ELEVIDYS treatment)
- Current or recent infections (within 4 weeks of ELEVIDYS treatment)

Who should not take ELEVIDYS?

You/Your child should not receive ELEVIDYS if they have a certain type of genetic mutation, called a deletion, involving any portion of or the entire exon 8 and/or exon 9 in the *DMD* gene.

Before taking ELEVIDYS, tell your child's doctor about all your child's medical conditions, including if they have:

- preexisting liver problems
- current or recent infection
- recent vaccinations (within 4 weeks)

How should your child receive ELEVIDYS?

- Before receiving ELEVIDYS, you/your child will need to get blood tests to check:
  - the amount of antibodies to ELEVIDYS
  - liver function
  - platelets, which is a kind of blood cell that helps you stop bleeding
  - heart protein
- Your/Your child's healthcare provider will give ELEVIDYS into a vein of the arm through an intravenous (IV) line that may last around 1 to 2 hours or longer.
- Your/Your child's healthcare provider will check on you/your child during and at least 3 hours after the infusion for infusion-related reactions. See **"What is the most important information I should know about ELEVIDYS?"** If an infusion-related reaction occurs during their ELEVIDYS infusion, your/your child's healthcare provider may decide to give ELEVIDYS more slowly or stop the infusion.

What are the possible side effects of ELEVIDYS?

- **ELEVIDYS can cause serious side effects. See "What is the most important information I should know about ELEVIDYS?"**
- **The most common side effects in individuals treated with ELEVIDYS include:**

- vomiting
- nausea
- liver injury
- fever
- lower number of platelets, which is a kind of blood cell that helps you stop bleeding
- higher levels of heart protein that can detect damage to muscle cells in the heart (troponin-I)

Tell your/your child's doctor about any side effects that bother you/your child or that do not go away. These are not all the possible side effects of ELEVIDYS.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
You may also report side effects to Sarepta Therapeutics, Inc. at 1-888-727-3782.

What should you/your child avoid after receiving ELEVIDYS?

- Avoid taking new medications that are known to damage the liver as this may make liver problems worse. **Tell your doctor about all the medicines you/your child takes,** including prescription and over-the counter medicines, vitamins, and herbal supplements.
- Discuss with your/your child's doctor before receiving a vaccine after ELEVIDYS treatment.
- Avoid missing any dose of corticosteroids. Contact your/your child's doctor immediately if this happens.

See **"What is the most important information I should know about ELEVIDYS?"**

General information about the safe and effective use of ELEVIDYS.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your/your child's pharmacist or doctor for information about ELEVIDYS that is written for health professionals.

What are the ingredients in ELEVIDYS?
Active ingredients: delandistrogene moxeparvovec-rokl

Inactive ingredients: sodium chloride, tromethamine hydrochloride, tromethamine, magnesium chloride, poloxamer 188

Manufactured for: Sarepta Therapeutics, Inc. Cambridge, MA 02142 USA U.S. license number 2308
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This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 11/2025

Principal Display Panel –Carton Kit Label

delandistrogene moxeparvovec-rokl

ELEVIDYS

1.33 x 10^{13} vector genomes/mL

Suspension for Infusion

For Intravenous Use

See enclosed prescribing information for dosage and administration instructions.

Preservative-free

Discard unused portion

Single patient use

Store unopened vials at ≤-60°C (-76°F) in original carton.

Unopened vials can be refrigerated for up to

14 days at 2°C to 8°C (36°F to 46°F).

DO NOT REFREEZE

DO NOT SHAKE

Rx Only

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SAREPTA

THERAPEUTICS

Principal Display Panel -10 mL 10 count Carton Label

NDC: 60923-501-10

delandistrogene moxeparvovec-rokl

ELEVIDYS

Patient Weight:

10.0 - 10.4 kg

Kit Contents:

10 x 10 mL vials

10 alcohol swabs

NDC: 60923-501-10

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
10.0 - 10.4 kg
Kit Contents:
10 x 10 mL vials
10 alcohol swabs

3 60923 50110 8

Date of refrigeration:

GTIN 00360923501108
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10087-01

Principal Display Panel -10 mL 11 count Carton Label

NDC: 60923-502-11

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

10.5 - 11.4 kg

Kit Contents:

11 x 10 mL vials

11 alcohol swabs

NDC: 60923-502-11

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
10.5 - 11.4 kg

Kit Contents:
11 x 10 mL vials
11 alcohol swabs

3 60923 50211 2

Date of refrigeration:

GTIN 00360923502112
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10088-01

Principal Display Panel -10 mL 12 count Carton Label

NDC: 60923-503-12

delandistrogene moxeparvovec-rokl

ELEVIDYS

Patient Weight:

11.5 - 12.4 kg

Kit Contents:

12 x 10 mL vials

12 alcohol swabs

NDC: 60923-503-12

delandistrogene moxeparvovec-rokl

ELEVIDYS

Patient Weight:
11.5 - 12.4 kg
Kit Contents:
12 x 10 mL vials
12 alcohol swabs

3 60923 50312 6

Date of refrigeration:

GTIN 00360923503126
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10089-01

Principal Display Panel -10 mL 13 count Carton Label

NDC: 60923-504-13

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:

12.5 - 13.4 kg

Kit Contents:

13 x 10 mL vials

13 alcohol swabs

Principal Display Panel -10 mL 14 count Carton Label

NDC: 60923-505-14

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:

13.5 - 14.4 kg

Kit Contents:

14 x 10 mL vials

14 alcohol swabs

NDC: 60923-505-14

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
13.5 - 14.4 kg
Kit Contents:
14 x 10 mL vials
14 alcohol swabs

3 60923 50514 4

Date of refrigeration:

GTIN 00360923505144
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10091-01

Principal Display Panel -10 mL 15 count Carton Label

NDC: 60923-506-15

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

14.5 - 15.4 kg

Kit Contents:

15 x 10 mL vials

15 alcohol swabs

NDC: 60923-506-15

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
14.5 - 15.4 kg
Kit Contents:
15 x 10 mL vials
15 alcohol swabs

Date of refrigeration:

GTIN 00360923506158
SN 000000000000
LOT 0000000
EXP YYYY-MMM

10092-01

Principal Display Panel -10 mL 16 count Carton Label

NDC: 60923-507-16

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

15.5 - 16.4 kg

Kit Contents:

16 x 10 mL vials

16 alcohol swabs

NDC: 60923-507-16

delandistrogene moxeparvovec-rokl

ELEVIDYS

Patient Weight:
15.5 - 16.4 kg
Kit Contents:
16 x 10 mL vials
16 alcohol swabs

3 60923 50716 2

Date of refrigeration:

GTIN 00360923507162
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10093-01

Principal Display Panel -10 mL 17 count Carton Label

NDC: 60923-508-17

delandistrogene

moxeparvovec-rokl
ELEVIDYS

Patient Weight:

16.5 - 17.4 kg

Kit Contents:

17 x 10 mL vials

17 alcohol swabs

NDC: 60923-508-17

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
16.5 - 17.4 kg
Kit Contents:
17 x 10 mL vials
17 alcohol swabs

3 60923 50817 6

Date of refrigeration:

GTIN 00360923508176
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10094-01

Principal Display Panel -10 mL 18 count Carton Label

NDC: 60923-509-18

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:

17.5 - 18.4 kg

Kit Contents:

18 x 10 mL vials

18 alcohol swabs

NDC: 60923-509-18

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
17.5 - 18.4 kg
Kit Contents:
18 x 10 mL vials
18 alcohol swabs

3 60923 50918 0

Date of refrigeration:

GTIN 00360923509180
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10095-01

Principal Display Panel -10 mL 19 count Carton Label

NDC: 60923-510-19

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

18.5 - 19.4 kg

Kit Contents:

19 x 10 mL vials

19 alcohol swabs

NDC: 60923-510-19

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
18.5 - 19.4 kg
Kit Contents:
19 x 10 mL vials
19 alcohol swabs

3 60923 51019 3

Date of refrigeration:

GTIN 00360923510193
SN 000000000000
LOT 0000000
EXP YYYY-MMM

Principal Display Panel -10 mL 20 count Carton Label

NDC: 60923-511-20

delandistrogene moxeparvovec-rokl

ELEVIDYS

Patient Weight:

19.5 - 20.4 kg

Kit Contents:

20 x 10 mL vials

20 alcohol swabs

NDC: 60923-511-20

delandistrogene moxeparvovec-rokl

ELEVIDYS

Patient Weight:
19.5 - 20.4 kg
Kit Contents:
20 x 10 mL vials
20 alcohol swabs

3 60923 51120 6

Date of refrigeration:

GTIN 00360923511206
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10097-01

Principal Display Panel -10 mL 21 count Carton Label

NDC: 60923-512-21

delandistrogene

moxeparvovec-rokl
ELEVIDYS

Patient Weight:

20.5 - 21.4 kg

Kit Contents:

21 x 10 mL vials

21 alcohol swabs

NDC: 60923-512-21

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:
20.5 - 21.4 kg
Kit Contents:
21 x 10 mL vials
21 alcohol swabs

3 60923 51221 0

Date of refrigeration:

GTIN 00360923512210
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10098-01

Principal Display Panel -10 mL 22 count Carton Label

NDC: 60923-513-22

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:

21.5 - 22.4 kg

Kit Contents:

22 x 10 mL vials

22 alcohol swabs

NDC: 60923-513-22

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
21.5 - 22.4 kg
Kit Contents:
22 x 10 mL vials
22 alcohol swabs

3 60923 51322 4

Date of refrigeration:

GTIN 00360923513224
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10099-01

Principal Display Panel -10 mL 23 count Carton Label

NDC: 60923-514-23

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

22.5 - 23.4 kg

Kit Contents:

23 x 10 mL vials

23 alcohol swabs

NDC: 60923-514-23

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
22.5 - 23.4 kg
Kit Contents:
23 x 10 mL vials
23 alcohol swabs

3 60923 51423 8

Date of refrigeration:

GTIN 00360923514238
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10100-01

Principal Display Panel -10 mL 24 count Carton Label

NDC: 60923-515-24

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

23.5 - 24.4 kg

Kit Contents:

24 x 10 mL vials

24 alcohol swabs

NDC: 60923-515-24

delandistrogene moxeparvovec-rokl

ELEVIDYS

Patient Weight:
23.5 - 24.4 kg

Kit Contents:
24 x 10 mL vials
24 alcohol swabs

3 60923 51524 2

Date of refrigeration:

GTIN 00360923515242
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10101-01

Principal Display Panel -10 mL 25 count Carton Label

NDC: 60923-516-25

delandistrogene

moxeparvovec-rokl
ELEVIDYS

Patient Weight:

24.5 - 25.4 kg

Kit Contents:

25 x 10 mL vials

25 alcohol swabs

NDC: 60923-516-25

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
24.5 - 25.4 kg
Kit Contents:
25 x 10 mL vials
25 alcohol swabs

3 60923 51625 6

Date of refrigeration:

GTIN 00360923516256
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10102-01

Principal Display Panel -10 mL 26 count Carton Label

NDC: 60923-517-26

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:

25.5 - 26.4 kg

Kit Contents:

26 x 10 mL vials

26 alcohol swabs

NDC: 60923-517-26

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
25.5 - 26.4 kg
Kit Contents:
26 x 10 mL vials
26 alcohol swabs

3 60923 51726 0

Date of refrigeration:

GTIN 00360923517260
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10103-01

Principal Display Panel -10 mL 27 count Carton Label

NDC: 60923-518-27

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

26.5 - 27.4 kg

Kit Contents:

27 x 10 mL vials

27 alcohol swabs

NDC: 60923-518-27

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
26.5 - 27.4 kg
Kit Contents:
27 x 10 mL vials
27 alcohol swabs

Date of refrigeration:

GTIN 00360923518274
SN 000000000000
LOT 0000000
EXP YYYY-MMM

10104-01

Principal Display Panel -10 mL 28 count Carton Label

NDC: 60923-519-28

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

27.5 - 28.4 kg

Kit Contents:

28 x 10 mL vials

28 alcohol swabs

NDC: 60923-519-28

delandistrogene moxeparvovec-rokl

ELEVIDYS

Patient Weight:
27.5 - 28.4 kg

Kit Contents:
28 x 10 mL vials
28 alcohol swabs

3 60923 51928 8

Date of refrigeration:

GTIN 00360923519288
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10105-01

Principal Display Panel -10 mL 29 count Carton Label

NDC: 60923-520-29

delandistrogene

moxeparvovec-rokl
ELEVIDYS

Patient Weight:

28.5 - 29.4 kg

Kit Contents:

29 x 10 mL vials

29 alcohol swabs

NDC: 60923-520-29

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:
28.5 - 29.4 kg
Kit Contents:
29 x 10 mL vials
29 alcohol swabs

3 60923 52029 1

Date of refrigeration:

GTIN 00360923520291
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10106-01

Principal Display Panel -10 mL 30 count Carton Label

NDC: 60923-521-30

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:

29.5 - 30.4 kg

Kit Contents:

30 x 10 mL vials

30 alcohol swabs

NDC: 60923-521-30

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
29.5 - 30.4 kg
Kit Contents:
30 x 10 mL vials
30 alcohol swabs

3 60923 52130 4

Date of refrigeration:

GTIN 00360923521304
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10107-01

Principal Display Panel -10 mL 31 count Carton Label

NDC: 60923-522-31

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

30.5 - 31.4 kg

Kit Contents:

31 x 10 mL vials

31 alcohol swabs

NDC: 60923-522-31

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
30.5 - 31.4 kg
Kit Contents:
31 x 10 mL vials
31 alcohol swabs

3 60923 52231 8

Date of refrigeration:

GTIN 00360923522318
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10108-01

Principal Display Panel -10 mL 32 count Carton Label

NDC: 60923-523-32

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

31.5 - 32.4 kg

Kit Contents:

32 x 10 mL vials

32 alcohol swabs

NDC: 60923-523-32

delandistrogene moxeparvovec-rokl

ELEVIDYS

Patient Weight:
31.5 - 32.4 kg

Kit Contents:
32 x 10 mL vials
32 alcohol swabs

3 60923 52332 2

Date of refrigeration:

GTIN 00360923523322
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10109-01

Principal Display Panel -10 mL 33 count Carton Label

NDC: 60923-524-33

delandistrogene

moxeparvovec-rokl
ELEVIDYS

Patient Weight:

32.5 - 33.4 kg

Kit Contents:

33 x 10 mL vials

33 alcohol swabs

NDC: 60923-524-33

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:
32.5 - 33.4 kg
Kit Contents:
33 x 10 mL vials
33 alcohol swabs

3 60923 52433 6

Date of refrigeration:

GTIN 00360923524336
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10110-01

Principal Display Panel -10 mL 34 count Carton Label

NDC: 60923-525-34

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:

33.5 - 34.4 kg

Kit Contents:

34 x 10 mL vials

34 alcohol swabs

NDC: 60923-525-34

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
33.5 - 34.4 kg
Kit Contents:
34 x 10 mL vials
34 alcohol swabs

3 60923 52534 0

Date of refrigeration:

GTIN 00360923525340
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10111-01

Principal Display Panel -10 mL 35 count Carton Label

NDC: 60923-526-35

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

34.5 - 35.4 kg

Kit Contents:

35 x 10 mL vials

35 alcohol swabs

NDC: 60923-526-35

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
34.5 - 35.4 kg
Kit Contents:
35 x 10 mL vials
35 alcohol swabs

3 60923 52635 4

Date of refrigeration:

GTIN 00360923526354
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10112-01

Principal Display Panel -10 mL 36 count Carton Label

NDC: 60923-527-36

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

35.5 - 36.4 kg

Kit Contents:

36 x 10 mL vials

36 alcohol swabs

NDC: 60923-527-36

delandistrogene moxeparvovec-rokl

ELEVIDYS

Patient Weight:
35.5 - 36.4 kg
Kit Contents:
36 x 10 mL vials
36 alcohol swabs

3 60923 52736 8

Date of refrigeration:

GTIN 00360923527368
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10113-01

Principal Display Panel -10 mL 37 count Carton Label

NDC: 60923-528-37

delandistrogene

moxeparvovec-rokl
ELEVIDYS

Patient Weight:

36.5 - 37.4 kg

Kit Contents:

37 x 10 mL vials

37 alcohol swabs

NDC: 60923-528-37

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:
36.5 - 37.4 kg
Kit Contents:
37 x 10 mL vials
37 alcohol swabs

3 60923 52837 2

Date of refrigeration:

GTIN 00360923528372
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10114-01

Principal Display Panel -10 mL 38 count Carton Label

NDC: 60923-529-38

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:

37.5 - 38.4 kg

Kit Contents:

38 x 10 mL vials

38 alcohol swabs

NDC: 60923-529-38

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
37.5 - 38.4 kg
Kit Contents:
38 x 10 mL vials
38 alcohol swabs

3 60923 52938 6

Date of refrigeration:

GTIN 00360923529386
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10115-01

Principal Display Panel -10 mL 39 count Carton Label

NDC: 60923-530-39

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

38.5 - 39.4 kg

Kit Contents:

39 x 10 mL vials

39 alcohol swabs

NDC: 60923-530-39

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
38.5 - 39.4 kg
Kit Contents:
39 x 10 mL vials
39 alcohol swabs

3 60923 53039 9

Date of refrigeration:

GTIN 00360923530399
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10116-01

Principal Display Panel -10 mL 40 count Carton Label

NDC: 60923-531-40

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

39.5 - 40.4 kg

Kit Contents:

40 x 10 mL vials

40 alcohol swabs

NDC: 60923-531-40

delandistrogene moxeparvovec-rokl

ELEVIDYS

Patient Weight:
39.5 - 40.4 kg
Kit Contents:
40 x 10 mL vials
40 alcohol swabs

3 60923 53140 2

Date of refrigeration:

GTIN 00360923531402
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10117-01

Principal Display Panel -10 mL 41 count Carton Label

NDC: 60923-532-41

delandistrogene

moxeparvovec-rokl
ELEVIDYS

Patient Weight:

40.5 - 41.4 kg

Kit Contents:

41 x 10 mL vials

41 alcohol swabs

NDC: 60923-532-41

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
40.5 - 41.4 kg
Kit Contents:
41 x 10 mL vials
41 alcohol swabs

3 60923 53241 6

Date of refrigeration:

GTIN 00360923532416
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10118-01

Principal Display Panel -10 mL 42 count Carton Label

NDC: 60923-533-42

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:

41.5 - 42.4 kg

Kit Contents:

42 x 10 mL vials

42 alcohol swabs

NDC: 60923-533-42

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
41.5 - 42.4 kg
Kit Contents:
42 x 10 mL vials
42 alcohol swabs

3 60923 53342 0

Date of refrigeration:

GTIN 00360923533420
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10119-01

Principal Display Panel -10 mL 43 count Carton Label

NDC: 60923-534-43

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

42.5 - 43.4 kg

Kit Contents:

43 x 10 mL vials

43 alcohol swabs

NDC: 60923-534-43

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
42.5 - 43.4 kg
Kit Contents:
43 x 10 mL vials
43 alcohol swabs

3 60923 53443 4

Date of refrigeration:

GTIN 00360923534434
SN 000000000000
LOT 0000000
EXP YYYY-MMM

10120-01

Principal Display Panel -10 mL 44 count Carton Label

NDC: 60923-535-44

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

43.5 - 44.4 kg

Kit Contents:

44 x 10 mL vials

44 alcohol swabs

NDC: 60923-535-44

delandistrogene moxeparvovec-rokl

ELEVIDYS

Patient Weight:
43.5 - 44.4 kg

Kit Contents:
44 x 10 mL vials
44 alcohol swabs

3 60923 53544 8

Date of refrigeration:

GTIN 00360923535448
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10121-01

Principal Display Panel -10 mL 45 count Carton Label

NDC: 60923-536-45

delandistrogene

moxeparvovec-rokl
ELEVIDYS

Patient Weight:

44.5 - 45.4 kg

Kit Contents:

45 x 10 mL vials

45 alcohol swabs

NDC: 60923-536-45

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:
44.5 - 45.4 kg
Kit Contents:
45 x 10 mL vials
45 alcohol swabs

3 60923 53645 2

Date of refrigeration:

GTIN 00360923536452
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10122-01

Principal Display Panel -10 mL 46 count Carton Label

NDC: 60923-537-46

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:

45.5 - 46.4 kg

Kit Contents:

46 x 10 mL vials

46 alcohol swabs

NDC: 60923-537-46

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
45.5 - 46.4 kg
Kit Contents:
46 x 10 mL vials
46 alcohol swabs

3 60923 53746 6

Date of refrigeration:

GTIN 00360923537466
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10123-01

Principal Display Panel -10 mL 47 count Carton Label

NDC: 60923-538-47

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

46.5 - 47.4 kg

Kit Contents:

47 x 10 mL vials

47 alcohol swabs

NDC: 60923-538-47

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
46.5 - 47.4 kg
Kit Contents:
47 x 10 mL vials
47 alcohol swabs

3 60923 53847 0

Date of refrigeration:

GTIN 00360923538470
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10124-01

Principal Display Panel -10 mL 48 count Carton Label

NDC: 60923-539-48

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

47.5 - 48.4 kg

Kit Contents:

48 x 10 mL vials

48 alcohol swabs

NDC: 60923-539-48

delandistrogene moxeparvovec-rokl

ELEVIDYS

Patient Weight:
47.5 - 48.4 kg

Kit Contents:
48 x 10 mL vials
48 alcohol swabs

3 60923 53948 4

Date of refrigeration:

GTIN 00360923539484
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10125-01

Principal Display Panel -10 mL 49 count Carton Label

NDC: 60923-540-49

delandistrogene

moxeparvovec-rokl
ELEVIDYS

Patient Weight:

48.5 - 49.4 kg

Kit Contents:

49 x 10 mL vials

49 alcohol swabs

NDC: 60923-540-49

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:
48.5 - 49.4 kg
Kit Contents:
49 x 10 mL vials
49 alcohol swabs

3 60923 54049 7

Date of refrigeration:

GTIN 00360923540497
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10126-01

Principal Display Panel -10 mL 50 count Carton Label

NDC: 60923-541-50

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:

49.5 - 50.4 kg

Kit Contents:

50 x 10 mL vials

50 alcohol swabs

NDC: 60923-541-50

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
49.5 - 50.4 kg

Kit Contents:
50 x 10 mL vials
50 alcohol swabs

3 60923 54150 0

Date of refrigeration:

GTIN 00360923541500
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10127-01

Principal Display Panel –Carton Kit Label

delandistrogene moxeparvovec-rokl

ELEVIDYS

1.33 x 10^{13} vector genomes/mL

Suspension for Infusion

For Intravenous Use

See enclosed prescribing information for dosage and administration instructions.

Preservative-free

Discard unused portion

Single patient use

Store unopened vials at ≤-60°C (-76°F) in original carton.

Unopened vials can be refrigerated for up to

14 days at 2°C to 8°C (36°F to 46°F).

DO NOT REFREEZE

DO NOT SHAKE

Rx Only

Manufactured for Sarepta Therapeutics, Inc., Cambridge, MA 02142 USA

US License No. 2308

Principal Display Panel –Carton Kit Label

delandistrogene moxeparvovec-rokl

ELEVIDYS

1.33 x 10^{13} vector genomes/mL

Suspension for Infusion

For Intravenous Use

See enclosed prescribing information for dosage and administration instructions.

Preservative-free

Discard unused

portion

Single patient use

Store unopened vials at ≤-60°C (-76°F) in original carton.

Unopened vials can be refrigerated for up to

14 days at 2°C to 8°C (36°F to 46°F).

DO NOT REFREEZE

DO NOT SHAKE

Rx Only

Manufactured for Sarepta Therapeutics, Inc., Cambridge, MA 02142 USA

US License No. 2308

Principal Display Panel –Vial Label

delandistrogene moxeparvovec-rokl

ELEVIDYS

1.33 x 10^{13} vector genomes/mL

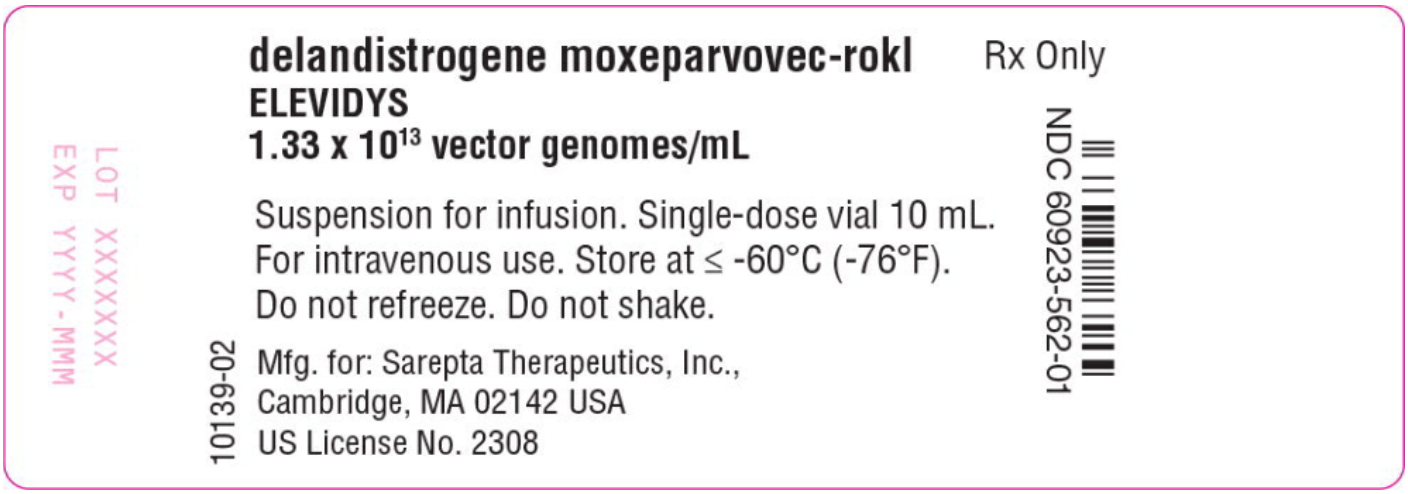
Suspension for infusion. Single-dose vial 10 mL.
For intravenous use. Store at ≤ -60°C (-76°F).

Do not refreeze. Do not shake.

Mfg. for: Sarepta Therapeutics, Inc.,
Cambridge, MA 02142 USA
US License No. 2308

Rx Only

NDC 60923-562-01



Principal Display Panel -10 mL 51 count Carton Label

NDC: 60923-542-51

**delandistrogene
moxeparvovec-rokl
ELEVIDYS**

Patient Weight:

50.5 - 51.4 kg

Kit Contents:

51 x 10 mL vials

51 alcohol swabs

NDC: 60923-542-51

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
50.5 - 51.4 kg
Kit Contents:
51 x 10 mL vials
51 alcohol swabs

3 60923 54251 4

Date of refrigeration:

GTIN 00360923542514
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10143-01

Principal Display Panel -10 mL 52 count Carton Label

NDC: 60923-543-52

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

51.5 - 52.4 kg

Kit Contents:

52 x 10 mL vials

52 alcohol swabs

NDC: 60923-543-52

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
51.5 - 52.4 kg
Kit Contents:
52 x 10 mL vials
52 alcohol swabs

Date of refrigeration:

GTIN 00360923543528
SN 000000000000
LOT 0000000
EXP YYYY-MMM

10144-01

Principal Display Panel -10 mL 53 count Carton Label

NDC: 60923-544-53

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

52.5 - 53.4 kg

Kit Contents:

53 x 10 mL vials

53 alcohol swabs

NDC: 60923-544-53

delandistrogene moxeparvovec-rokl

ELEVIDYS

Patient Weight:
52.5 - 53.4 kg

Kit Contents:
53 x 10 mL vials
53 alcohol swabs

3 60923 54453 2

Date of refrigeration:

GTIN 00360923544532
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10145-01

Principal Display Panel -10 mL 54 count Carton Label

NDC: 60923-545-54

delandistrogene

moxeparvovec-rokl
ELEVIDYS

Patient Weight:

53.5 - 54.4 kg

Kit Contents:

54 x 10 mL vials

54 alcohol swabs

NDC: 60923-545-54

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
53.5 - 54.4 kg
Kit Contents:
54 x 10 mL vials
54 alcohol swabs

3 60923 54554 6

Date of refrigeration:

GTIN 00360923545546
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10146-01

Principal Display Panel -10 mL 55 count Carton Label

NDC: 60923-546-55

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:

54.5 - 55.4 kg

Kit Contents:

55 x 10 mL vials

55 alcohol swabs

NDC: 60923-546-55

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
54.5 - 55.4 kg
Kit Contents:
55 x 10 mL vials
55 alcohol swabs

3 60923 54655 0

Date of refrigeration:

GTIN 00360923546550
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10147-01

Principal Display Panel -10 mL 56 count Carton Label

NDC: 60923-547-56

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

55.5 - 56.4 kg

Kit Contents:

56 x 10 mL vials

56 alcohol swabs

NDC: 60923-547-56

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
55.5 - 56.4 kg
Kit Contents:
56 x 10 mL vials
56 alcohol swabs

Date of refrigeration:

GTIN 00360923547564
SN 000000000000
LOT 0000000
EXP YYYY-MMM

10148-01

Principal Display Panel -10 mL 57 count Carton Label

NDC: 60923-548-57

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

56.5 - 57.4 kg

Kit Contents:

57 x 10 mL vials

57 alcohol swabs

NDC: 60923-548-57

delandistrogene moxeparvovec-rokl

ELEVIDYS

Patient Weight:
56.5 - 57.4 kg
Kit Contents:
57 x 10 mL vials
57 alcohol swabs

3 60923 54857 8

Date of refrigeration:

GTIN 00360923548578
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10149-01

Principal Display Panel -10 mL 58 count Carton Label

NDC: 60923-549-58

delandistrogene

moxeparvovec-rokl
ELEVIDYS

Patient Weight:

57.5 - 58.4 kg

Kit Contents:

58 x 10 mL vials

58 alcohol swabs

NDC: 60923-549-58

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
57.5 - 58.4 kg
Kit Contents:
58 x 10 mL vials
58 alcohol swabs

3 60923 54958 2

Date of refrigeration:

GTIN 00360923549582
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10150-01

Principal Display Panel -10 mL 59 count Carton Label

NDC: 60923-550-59

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:

58.5 - 59.4 kg

Kit Contents:

59 x 10 mL vials

59 alcohol swabs

NDC: 60923-550-59

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
58.5 - 59.4 kg
Kit Contents:
59 x 10 mL vials
59 alcohol swabs

3 60923 55059 5

Date of refrigeration:

GTIN 00360923550595
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10151-01

Principal Display Panel -10 mL 60 count Carton Label

NDC: 60923-551-60

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

59.5 - 60.4 kg

Kit Contents:

60 x 10 mL vials

60 alcohol swabs

NDC: 60923-551-60

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
59.5 - 60.4 kg
Kit Contents:
60 x 10 mL vials
60 alcohol swabs

3 60923 55160 8

Date of refrigeration:

GTIN 00360923551608
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10152-01

Principal Display Panel -10 mL 61 count Carton Label

NDC: 60923-552-61

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

60.5 - 61.4 kg

Kit Contents:

61 x 10 mL vials

61 alcohol swabs

NDC: 60923-552-61

delandistrogene moxeparvovec-rokl

ELEVIDYS

Patient Weight:
60.5 - 61.4 kg
Kit Contents:
61 x 10 mL vials
61 alcohol swabs

3 60923 55261 2

Date of refrigeration:

GTIN 00360923552612
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10153-01

Principal Display Panel -10 mL 62 count Carton Label

NDC: 60923-553-62

delandistrogene

moxeparvovec-rokl
ELEVIDYS

Patient Weight:

61.5 - 62.4 kg

Kit Contents:

62 x 10 mL vials

62 alcohol swabs

NDC: 60923-553-62

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
61.5 - 62.4 kg
Kit Contents:
62 x 10 mL vials
62 alcohol swabs

3 60923 55362 6

Date of refrigeration:

GTIN 00360923553626
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10154-01

Principal Display Panel -10 mL 63 count Carton Label

NDC: 60923-554-63

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:

62.5 - 63.4 kg

Kit Contents:

63 x 10 mL vials

63 alcohol swabs

NDC: 60923-554-63

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
62.5 - 63.4 kg
Kit Contents:
63 x 10 mL vials
63 alcohol swabs

3 60923 55463 0

Date of refrigeration:

GTIN 00360923554630
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10155-01

Principal Display Panel -10 mL 64 count Carton Label

NDC: 60923-555-64

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

63.5 - 64.4 kg

Kit Contents:

64 x 10 mL vials

64 alcohol swabs

NDC: 60923-555-64

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
63.5 - 64.4 kg
Kit Contents:
64 x 10 mL vials
64 alcohol swabs

3 60923 55564 4

Date of refrigeration:

GTIN 00360923555644
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10156-01

Principal Display Panel -10 mL 65 count Carton Label

NDC: 60923-556-65

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

64.5 - 65.4 kg

Kit Contents:

65 x 10 mL vials

65 alcohol swabs

NDC: 60923-556-65

delandistrogene moxeparvovec-rokl

ELEVIDYS

Patient Weight:
64.5 - 65.4 kg

Kit Contents:
65 x 10 mL vials
65 alcohol swabs

3 60923 55665 8

Date of refrigeration:

GTIN 00360923556658
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10157-01

Principal Display Panel -10 mL 66 count Carton Label

NDC: 60923-557-66

delandistrogene

moxeparvovec-rokl
ELEVIDYS

Patient Weight:

65.5 - 66.4 kg

Kit Contents:

66 x 10 mL vials

66 alcohol swabs

NDC: 60923-557-66

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
65.5 - 66.4 kg
Kit Contents:
66 x 10 mL vials
66 alcohol swabs

3 60923 55766 2

Date of refrigeration:

GTIN 00360923557662
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10158-01

Principal Display Panel -10 mL 67 count Carton Label

NDC: 60923-558-67

delandistrogene moxeparvovec-rokl
ELEVIDYS

Patient Weight:

66.5 - 67.4 kg

Kit Contents:

67 x 10 mL vials

67 alcohol swabs

NDC: 60923-558-67

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
66.5 - 67.4 kg
Kit Contents:
67 x 10 mL vials
67 alcohol swabs

3 60923 55867 6

Date of refrigeration:

GTIN 00360923558676
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10159-01

Principal Display Panel -10 mL 68 count Carton Label

NDC: 60923-559-68

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

67.5 - 68.4 kg

Kit Contents:

68 x 10 mL vials

68 alcohol swabs

NDC: 60923-559-68

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:
67.5 - 68.4 kg
Kit Contents:
68 x 10 mL vials
68 alcohol swabs

Date of refrigeration:

GTIN 00360923559680
SN 000000000000
LOT 0000000
EXP YYYY-MMM

10160-01

Principal Display Panel -10 mL 69 count Carton Label

NDC: 60923-560-69

delandistrogene moxeparvovec-rokl ELEVIDYS

Patient Weight:

68.5 - 69.4 kg

Kit Contents:

69 x 10 mL vials

69 alcohol swabs

NDC: 60923-560-69

delandistrogene moxeparvovec-rokl

ELEVIDYS

Patient Weight:
68.5 - 69.4 kg
Kit Contents:
69 x 10 mL vials
69 alcohol swabs

3 60923 56069 3

Date of refrigeration:

GTIN 00360923560693
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10161-01

Principal Display Panel -10 mL 70 count Carton Label

NDC: 60923-561-70

delandistrogene

moxeparvovec-rokl
ELEVIDYS

Patient Weight:

69.5 kg and
above

Kit Contents:

70 x 10 mL vials

70 alcohol swabs

NDC: 60923-561-70

delandistrogene
moxeparvovec-rokl
ELEVIDYS

Patient Weight:
69.5 kg and
above
Kit Contents:
70 x 10 mL vials
70 alcohol swabs

3 60923 56170 6

Date of refrigeration:

GTIN 00360923561706
SN 000000000000
LOT 0000000
EXP YYYY-MMM

FPO

10162-01

Principal Display Panel – 10 mL Vial Label

NDC: 60923-562-01

delandistrogene moxeparvovec-rokl

ELEVIDYS

1.33×10^{13} vector genomes/mL

Suspension for Infusion

For Intravenous Use

See enclosed prescribing information
for dosage and administration instructions.

Rx Only

Single-dose

1 vial

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60923-501

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-501-10	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity

Part 1	10 VIAL, SINGLE-USE	100 mL
Part 2	10 POUCH	10

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		10 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-502

Packaging				

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-502-11	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	11 VIAL, SINGLE-USE	110 mL
Part 2	11 POUCH	11

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		11 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-503

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-503-12	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	12 VIAL, SINGLE-USE	120 mL
Part 2	12 POUCH	12

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		12 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60923-504

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-504-13	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	13 VIAL, SINGLE-USE	130 mL
Part 2	13 POUCH	13

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	

Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		13 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-505

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-505-14	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	14 VIAL, SINGLE-USE	140 mL
Part 2	14 POUCH	14

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item**	**Package Description**	**Marketing Start**	**Marketing End**

#	Code	Package Description	Date	Date
1		14 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-506

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-506-15	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	15 VIAL, SINGLE-USE	150 mL
Part 2	15 POUCH	15

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		15 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-507

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-507-16	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	16 VIAL, SINGLE-USE	160 mL
Part 2	16 POUCH	16

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563

Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		16 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-508

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-508-17	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	17 VIAL, SINGLE-USE	170 mL
Part 2	17 POUCH	17

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		17 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-509

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-509-18	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	18 VIAL, SINGLE-USE	180 mL
Part 2	18 POUCH	18

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		18 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-510

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-510-19	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	19 VIAL, SINGLE-USE	190 mL
Part 2	19 POUCH	19

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		19 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-511

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-511-20	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	20 VIAL, SINGLE-USE	200 mL
Part 2	20 POUCH	20

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	

Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		20 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-512

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-512-21	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	21 VIAL, SINGLE-USE	210 mL
Part 2	21 POUCH	21

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		21 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-513

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-513-22	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	22 VIAL, SINGLE-USE	220 mL
Part 2	22 POUCH	22

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		22 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-514

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-514-23	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	23 VIAL, SINGLE-USE	230 mL
Part 2	23 POUCH	23

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		23 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60923-515

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-515-24	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	24 VIAL, SINGLE-USE	240 mL
Part 2	24 POUCH	24

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		24 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-516

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-516-25	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	25 VIAL, SINGLE-USE	250 mL
Part 2	25 POUCH	25

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		25 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-517

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-517-26	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	26 VIAL, SINGLE-USE	260 mL
Part 2	26 POUCH	26

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		26 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-518

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-518-27	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	27 VIAL, SINGLE-USE	270 mL
Part 2	27 POUCH	27

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	

Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		27 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-519

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-519-28	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	28 VIAL, SINGLE-USE	280 mL
Part 2	28 POUCH	28

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		28 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-520

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-520-29	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	29 VIAL, SINGLE-USE	290 mL
Part 2	29 POUCH	29

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		29 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-521

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-521-30	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	30 VIAL, SINGLE-USE	300 mL
Part 2	30 POUCH	30

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60923-522

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-522-31	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	31 VIAL, SINGLE-USE	310 mL
Part 2	31 POUCH	31

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		31 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-523

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-523-32	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	32 VIAL, SINGLE-USE	320 mL
Part 2	32 POUCH	32

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		32 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-524

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-524-33	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	33 VIAL, SINGLE-USE	330 mL
Part 2	33 POUCH	33

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		33 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-525

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-525-34	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	34 VIAL, SINGLE-USE	340 mL
Part 2	34 POUCH	34

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	

Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		34 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-526

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-526-35	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	35 VIAL, SINGLE-USE	350 mL
Part 2	35 POUCH	35

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		35 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-527

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-527-36	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	36 VIAL, SINGLE-USE	360 mL
Part 2	36 POUCH	36

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		36 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-528

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-528-37	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	37 VIAL, SINGLE-USE	370 mL
Part 2	37 POUCH	37

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		37 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60923-529

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-529-38	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	38 VIAL, SINGLE-USE	380 mL
Part 2	38 POUCH	38

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		38 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-530

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-530-39	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	39 VIAL, SINGLE-USE	390 mL
Part 2	39 POUCH	39

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		39 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-531

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-531-40	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	40 VIAL, SINGLE-USE	400 mL
Part 2	40 POUCH	40

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		40 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-532

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-532-41	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	41 VIAL, SINGLE-USE	410 mL
Part 2	41 POUCH	41

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	

Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		41 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-533

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-533-42	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	42 VIAL, SINGLE-USE	420 mL
Part 2	42 POUCH	42

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		42 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-534

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-534-43	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	43 VIAL, SINGLE-USE	430 mL
Part 2	43 POUCH	43

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		43 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-535

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-535-44	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	44 VIAL, SINGLE-USE	440 mL
Part 2	44 POUCH	44

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		44 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60923-536

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-536-45	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	45 VIAL, SINGLE-USE	450 mL
Part 2	45 POUCH	45

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		45 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-537

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-537-46	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	46 VIAL, SINGLE-USE	460 mL
Part 2	46 POUCH	46

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		46 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-538

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-538-47	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	47 VIAL, SINGLE-USE	470 mL
Part 2	47 POUCH	47

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		47 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-539

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-539-48	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	48 VIAL, SINGLE-USE	480 mL
Part 2	48 POUCH	48

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	

Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		48 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-540

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-540-49	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	49 VIAL, SINGLE-USE	490 mL
Part 2	49 POUCH	49

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		49 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-541

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-541-50	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	50 VIAL, SINGLE-USE	500 mL
Part 2	50 POUCH	50

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		50 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-542

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-542-51	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	51 VIAL, SINGLE-USE	510 mL
Part 2	51 POUCH	51

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563

Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		51 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-543

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-543-52	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	52 VIAL, SINGLE-USE	520 mL
Part 2	52 POUCH	52

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		52 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-544

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-544-53	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	53 VIAL, SINGLE-USE	530 mL
Part 2	53 POUCH	53

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		53 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-545

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-545-54	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	54 VIAL, SINGLE-USE	540 mL
Part 2	54 POUCH	54

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		54 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-546

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-546-55	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	55 VIAL, SINGLE-USE	550 mL
Part 2	55 POUCH	55

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	

Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		55 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-547

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-547-56	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	56 VIAL, SINGLE-USE	560 mL
Part 2	56 POUCH	56

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		56 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-548

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-548-57	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	57 VIAL, SINGLE-USE	570 mL
Part 2	57 POUCH	57

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		57 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-549

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-549-58	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	58 VIAL, SINGLE-USE	580 mL
Part 2	58 POUCH	58

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563

Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		58 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-550

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-550-59	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	59 VIAL, SINGLE-USE	590 mL
Part 2	59 POUCH	59

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		59 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-551

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-551-60	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	60 VIAL, SINGLE-USE	600 mL
Part 2	60 POUCH	60

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		60 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-552

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-552-61	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	61 VIAL, SINGLE-USE	610 mL
Part 2	61 POUCH	61

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		61 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-553

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-553-62	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	62 VIAL, SINGLE-USE	620 mL
Part 2	62 POUCH	62

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	

Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		62 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-554

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-554-63	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	63 VIAL, SINGLE-USE	630 mL
Part 2	63 POUCH	63

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		63 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-555

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-555-64	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	64 VIAL, SINGLE-USE	640 mL
Part 2	64 POUCH	64

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		64 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-556

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-556-65	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	65 VIAL, SINGLE-USE	650 mL
Part 2	65 POUCH	65

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		65 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60923-557

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-557-66	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	66 VIAL, SINGLE-USE	660 mL
Part 2	66 POUCH	66

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		66 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-558

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-558-67	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	67 VIAL, SINGLE-USE	670 mL
Part 2	67 POUCH	67

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		67 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-559

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60923-559-68	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	68 VIAL, SINGLE-USE	680 mL
Part 2	68 POUCH	68

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information	
Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		68 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-560

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-560-69	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	69 VIAL, SINGLE-USE	690 mL
Part 2	69 POUCH	69

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium chloride (UNII: 451W47IQ8X)	

Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		69 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

ELEVIDYS

delandistrogene moxeparvovec-rokl kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60923-561

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-561-70	1 in 1 CARTON; Type 0: Not a Combination Product	06/22/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	70 VIAL, SINGLE-USE	700 mL
Part 2	70 POUCH	70

Part 1 of 2

ELEVIDYS

delandistrogene moxeparvovec-rokl injection, suspension

Product Information

Item Code (Source)	NDC:60923-562
Route of Administration	INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

delandistrogene moxeparvovec (UNII: 2P6QV2ZE52) (delandistrogene moxeparvovec - UNII:2P6QV2ZE52)	delandistrogene moxeparvovec	13300000000000 {GC} in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium chloride (UNII: 451W47IQ8X)	
Tromethamine Hydrochloride (UNII: 383V75M34E)	
Tromethamine (UNII: 023C2WHX2V)	
Magnesium chloride (UNII: 02F3473H9O)	
Poloxamer 188 (UNII: LQA7B6G8JG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60923-562-01	10 mL in 1 VIAL, SINGLE-USE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Part 2 of 2

ISOPROPYL ALCOHOL SWABS

isopropyl alcohol swab

Product Information	
Item Code (Source)	NDC:60923-563
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	0.75 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		70 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	06/22/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125781	06/22/2023	

Labeler - Sarepta Therapeutics, Inc. (121653406)

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