KOATE - antihemophilic factor (human) KOATE - antihemophilic factor (human) KEDRION BIOPHARMA, INC.

HIGHLIGHTS OF PRESCRIBING INFORMATION These highlights do not include all the information needed to use KOĀTE [®] safely and effectively. See full prescribing information for KOĀTE.
KOĀTE [®] , Antihemophilic Factor (Human) Lyophilized Powder for Solution for Intravenous Injection Initial U.S. Approval: 1974
KOĀTE is a human plasma-derived antihemophilic factor indicated for the control and prevention of bleeding episodes or in order to perform emergency and elective surgery in patients with hemophilia A (hereditary Factor VIII deficiency). (1)
Limitation of Use KOĀTE is not indicated for the treatment of von Willebrand disease. DOSAGE AND ADMINISTRATION
 For intravenous use after reconstitution only. Each vial of KOĀTE contains the labeled amount of Factor VIII in international units (IU). (2) Required Dose (IU) = Body Weight (kg) x Desired Factor VIII Rise (IU/dL or % of normal) x 0.5 Frequency of KOĀTE administration is determined by the type of bleeding episode and the recommendation of the treating physician.
DOSAGE FORMS AND STRENGTHS KOĀTE is available as a lyophilized powder for reconstitution in single-use vials of 250, 500, and 1,000 international units of Factor VIII activity. (3)
Do not use in patients who have known hypersensitivity reactions, including anaphylaxis, to KOĀTE or its components. (4)
 WARNINGS AND PRECAUTIONS Hypersensitivity reactions, including anaphylaxis, are possible. Should symptoms occur, discontinue KOĀTE and administer appropriate treatment. (5.1) Development of neutralizing antibodies (inhibitors) may occur. If expected plasma Factor VIII activity levels are not attained, or if bleeding is not controlled with an appropriate dose, perform an assay that measures Factor VIII inhibitor concentration. (5.2) Monitor for intravascular hemolysis and decreasing hematocrit values in patients with A, B or AB blood groups who are receiving large or frequent doses. (5.3) KOĀTE is made from human blood and therefore carries a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. (5.4)
The most common adverse drug reactions (frequency ≥ 5% of subjects) observed in the clinical trial were nervousness, headache, abdominal pain, nausea, paresthesia and blurred vision. (6) To report SUSPECTED ADVERSE REACTIONS, contact Grifols Therapeutics LLC at 1-800-520-2807 or FDA at 1-800-FDA-1088 or http://www.fda.gov/medwatch.
USE IN SPECIFIC POPULATIONS Pediatric: clearance of Factor VIII (based on per kilogram body weight) is higher in children. Higher or more frequent dosing may be needed. (8.4) See 17 for PATIENT COUNSELING INFORMATION. Revised: 1/2022

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FULL PRESCRIBING INFORMATION

1 Indications and Usage

KOĀTE[®] is a human plasma-derived antihemophilic factor indicated for the control and prevention of bleeding episodes or in order to perform emergency and elective surgery in patients with hemophilia A (hereditary Factor VIII deficiency).

Limitation of Use

KOĀTE is not indicated for the treatment of von Willebrand disease.

2 Dosage and Administration

For intravenous use after reconstitution only.

2.1 Dose

- Dose and duration of treatment depend on the severity of the Factor VIII deficiency, location and extent of bleeding, and the patient's clinical condition.
- Each vial of KOĀTE is labeled with the actual Factor VIII potency in international units (IU). Calculation of the required dose of Factor VIII is based on the empirical finding that one IU of Factor VIII per kg body weight raises the plasma Factor VIII activity by approximately 2% of normal activity or 2 IU/dL.
- The required dose can be determined using the following formula:

Dose (IU) = Body Weight (kg) x Desired Factor VIII Rise (% normal or IU/dL) x 0.5

 Estimate the expected in vivo peak increase in Factor VIII level, expressed as IU/dL (or % normal), using the following formula:

Estimated Increment of Factor VIII (% normal or IU/dL) = [Total Dose (IU)/Body Weight (kg)] x 2

• Patients may vary in their pharmacokinetic (e.g., half-life, in vivo recovery) and clinical responses. Base the dose and frequency on the individual clinical response.

Control and Prevention of Bleeding Episodes

A guide for dosing KOĀTE for the control and prevention of bleeding episodes (1,2) is provided in Table 1. Consideration should be given to maintaining a Factor VIII activity at or above the target range.

Type of Bleeding	Factor VIII:C Level Required (% of normal)	Doses (IU/kg)	Frequency of Doses (hours)	Duration of Therapy (days)
Minor Large bruises Significant cuts or scrapes Uncomplicated joint hemorrhage	30	15	12 (twice daily)	Until hemorrhage stops and healing has been achieved (1–2 days).
Moderate Nose, mouth	50	25	12	Until healing has been

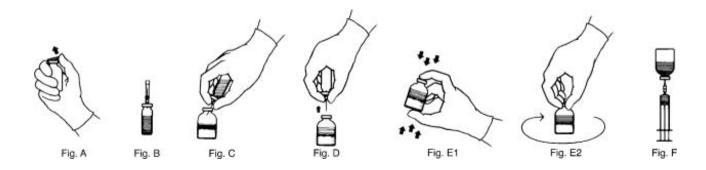
Table 1: Dosage Guidelines for Patients with Hemophilia A

and gum bleeds Dental extractions Hematuria			(twice daily)	achieved (2–7 days, on average).
	00.100		10	Fan at least
Major Joint	80-100	Initial: 40-50	12	For at least 3-5 days
hemorrhage		Maintenance:	(twice daily)	
Muscle hemorrhage		25	(twice daily)	Until healing has been achieved for
Major trauma				up to 10
Hematuria				days. Intracranial
Intracranial and intraperitoneal bleeding				hemorrhage may require prophylaxis therapy for up to 6 months.
Surgery	Prior to surgery:	40-50	Once	Prior to surgery
	80-100			Surgery
		30-50	12	
	After surgery: 60-100		(twice daily)	For the next 7-10 days, or until healing has been achieved.

2.2 Preparation and Reconstitution

- 1. Use aseptic technique (clean and sanitized) and a flat work surface during the reconstitution procedure.
- 2. Bring the vials of KOĀTE and the diluent (Sterile Water for Injection) to room temperature before use.
- 3. Remove the shrink band from the KOĀTE vial. Do not use KOĀTE if the shrink band is absent or shows signs of tampering, and notify Grifols Therapeutics LLC immediately.
- 4. Remove the plastic cap from the KOĀTE vial (Fig. A) and clean the top of the stopper with an alcohol swab. Allow the stopper to dry.
- 5. Repeat this step with the vial of sterile water.
- 6. Carefully remove the plastic sheath from the short end of the transfer needle and insert the exposed needle into the diluent vial to the hub (Fig. B)
- 7. Place the KOĀTE vial upright on a flat surface. Remove the sheath from the other end of the transfer needle.

- 8. While holding the KOĀTE vial securely on a flat surface insert the needle into the vial at a 45° angle to minimize foaming (Fig. C). The vacuum will draw the diluent into the concentrate vial. If vacuum is lost, use a sterile syringe and needle to remove the sterile water from the diluent vial and inject it into the KOĀTE, directing the stream of fluid against the wall of the vial.
- 9. Remove the diluent vial and transfer needle (Fig. D).
- Agitate vigorously for 10-15 seconds, (Fig. E1) then swirl continuously until completely dissolved (Fig. E2). Avoid excessive foaming. The reconstituted solution should be clear to opalescent. Do not use if particulate matter and discoloration is observed.
- 11. Clean the top of the vial of reconstituted KOĀTE with alcohol swab and let surface dry.
- 12. Attach the filter needle (from the package) to a sterile syringe. Withdraw the KOĀTE solution into the syringe through the filter needle (Fig. F).
- 13. Remove the filter needle from the syringe and discard the filter needle into a puncture proof container. Use KOĀTE within 3 hours after reconstitution. Do not refrigerate after reconstitution.



2.3 Administration

For intravenous administration only

- If the dose requires more than one vial of KOĀTE:
 - Reconstitute each vial using a new transfer needle.
 - Draw up all the solution into a single syringe.
- Visually inspect the final solution for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if particulate matter or discoloration is observed.
- Attach the syringe to the connector end of an infusion set.
- Administer intravenously. The rate of administration should be determined by the patient's comfort level, and no faster than 10 mL per minute.

3 DOSAGE FORMS AND STRENGTHS

KOĀTE is available as a lyophilized powder for reconstitution in single-use vials of 250, 500 and 1,000 IU of Factor VIII activity. The actual Factor VIII potency is labeled on each KOĀTE vial.

4 CONTRAINDICATIONS

KOĀTE is contraindicated in patients who have had hypersensitivity reactions, including anaphylaxis, to KOĀTE or its components.[see Description (11)]

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis, are possible. Early signs of hypersensitivity reactions, which can progress to anaphylaxis, may include angioedema, chest tightness, hypotension, rash, nausea, vomiting, paresthesia, restlessness, wheezing and dyspnea. If hypersensitivity symptoms occur, discontinue use of the product immediately and administer appropriate emergency treatment.

5.2 Neutralizing Antibodies

The formation of neutralizing antibodies (inhibitors) to Factor VIII may occur. Monitor all patients for the development of Factor VIII inhibitors by appropriate clinical observations and laboratory tests. If expected plasma Factor VIII activity levels are not attained, or if bleeding is not controlled with an appropriate dose, perform an assay that measures Factor VIII inhibitor Concentration. *[see Warnings and Precautions (5.5)]*

5.3 Intravascular Hemolysis

KOĀTE contains blood group isoagglutinins which are not clinically significant when small doses are used to treat minor bleeding episodes. However, when large and/or frequent doses of KOĀTE are given to patients with blood groups A, B, or AB, acute hemolytic anemia may occur, resulting in increased bleeding tendency or hyperfibrinogenemia. Monitor these patients for signs of intravascular hemolysis and falling hematocrit. [see Warnings and Precautions (5.5)] Should this condition occur, leading to progressive hemolytic anemia, discontinue KOĀTE and consider administering serologically compatible Type O red blood cells and providing alternative therapy.

5.4 Transmissible Infectious Agents

Because KOĀTE is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. There is also the possibility that unknown infectious agents may be present in the product. The risk that the product will transmit viruses has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and removing certain viruses during manufacture. Despite these measures, this product may still potentially transmit diseases.

Report all infections suspected by a physician possibly to have been transmitted by this product to Grifols Therapeutics LLC at 1-800-520-2807.

5.5 Monitoring: Laboratory Tests

- Monitor plasma Factor VIII activity levels by performing a validated test (e.g., onestage clotting assay) to confirm that adequate Factor VIII levels have been achieved and maintained. [see Dosage ad Administration (2.1)]
- Monitor for the development of Factor VIII inhibitors. Perform a Bethesda inhibitor

assay if expected Factor VIII plasma levels are not attained, or if bleeding is not controlled with the expected dose of KOĀTE. Use Bethesda Units (BU) to report inhibitor levels.

• Monitor for intravascular hemolysis and decreasing hematocrit values in patients with A, B or AB blood groups who are receiving large or frequent doses of KOĀTE.

6 ADVERSE REACTIONS

The most common adverse drug reactions (frequency \geq 5 % of subjects) observed in the clinical trial were nervousness, headache, abdominal pain, nausea, paresthesia and blurred vision.

6.1 Clinical Trials Experience

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

The safety assessment of KOĀTE is based on data from a 2-stage, safety, pharmacokinetic (PK) and efficacy clinical trial in which twenty subjects with severe hemophilia A (<1% endogenous Factor VIII activity) were evaluable for safety. Nineteen subjects were enrolled in Stage I of the trial, including 15 Caucasian, 3 Hispanic, and 1 Black subjects. The mean age was 29 years (range: 13.9 – 46.4 years). Nineteen subjects, including the 18 subjects who completed Stage I, and one new subject were enrolled in Stage II. The mean age was 30 years (range: 13.9 – 46.4). The subjects received a total of 1053 infusions. Ten adverse reactions related to 7 infusions were reported in 4 subjects. These were: nervousness (2 subjects [10%]), headache (1 subject [5%]), abdominal pain (1 subject [5%]), nausea (1 subject [5%]), paresthesia (1 subject [5%]), and blurred vision (1 subject [5%]).

Immunogenicity

Subjects were monitored for neutralizing antibodies (inhibitors) to Factor VIII by the Bethesda assay at baseline and at 8, 17 and 26 weeks. No evidence of inhibitor formation was observed in the clinical trial.

The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, it may be misleading to compare the incidence of antibodies to KOĀTE in the study described above with the incidence of antibodies in other studies or to other products.

6.2 Postmarketing Experience

Because postmarketing reporting of adverse reactions is voluntary and from a population of uncertain size, it is not always possible to reliably estimate the frequency of these reactions or establish a causal relationship to product exposure.

- Blood and Lymphatic System Disorders: Factor VIII inhibition, hemolytic anemia
- Immune System Disorders: Hypersensitivity including anaphylaxis, rash, pruritus

- Injury, Poisoning and Procedural Complications: Post-procedural hemorrhage
- Nervous System Disorders: Generalized clonic-tonic seizure

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

<u>Risk Summary</u>

There are no data with KOĀTE use in pregnant women to inform on drug-associated risk. Animal reproduction studies have not been conducted using KOĀTE. It is not known whether KOĀTE can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. KOĀTE should be given to a pregnant woman only if clearly needed. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

8.2 Lactation

<u>Risk Summary</u>

There is no information regarding the presence of KOĀTE in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for KOĀTE and any potential adverse effects on the breast-fed infant from KOĀTE or from the underlying maternal condition.

8.4 Pediatric Use

Safety and efficacy studies have been performed in 20 previously treated pediatric patients aged 2.5 to 16 years. Subjects received 208 infusions of KOĀTE for treatment or control of bleeding episodes, including perioperative management, and routine prophylaxis. Children have shorter half-life and lower recovery of Factor VIII than adults. Because clearance of Factor VIII (based on per kilogram body weight) is higher in children, higher or more frequent dosing may be needed.

8.5 Geriatric Use

Clinical studies of KOĀTE did not include any subjects aged 65 and over to determine whether they respond differently from younger subjects. Individualize dose selection for geriatric patients.

11 DESCRIPTION

KOĀTE, Antihemophilic Factor (Human), is a sterile, stable, dried concentrate of human antihemophilic factor in lyophilized powder form for reconstitution for intravenous injection. The product is supplied in single-use vials containing nominally 250, 500, or 1,000 international units (IU or units). Each vial of KOĀTE is labeled with the actual amount of Factor VIII expressed in IU. One IU is defined by the current World Health Organization International Standard for Factor VIII concentrate, which can be traced to the level of Factor VIII found in 1 mL of fresh pooled human plasma. The final product when reconstituted as directed contains not more than (NMT) 1500 µg/mL polyethylene glycol (PEG), NMT 0.05 M glycine, NMT 25 μ g/mL polysorbate 80, NMT 5 μ g/g tri-n-butyl phosphate (TNBP), NMT 3 mM calcium, NMT 1 μ g/mL aluminum, NMT 0.06 M histidine, and NMT 10 mg/mL human albumin.

KOĀTE is purified from the cold insoluble fraction of pooled human plasma; the manufacturing process includes solvent/detergent (TNBP and polysorbate 80) treatment and heat treatment of the lyophilized final container. A gel permeation chromatography step serves the dual purpose of reducing the amount of TNBP and polysorbate 80 as well as increasing the purity of the Factor VIII in KOĀTE to 300 to 1,000 times over whole plasma. When reconstituted as directed, KOĀTE contains approximately 50 to 150 times as much Factor VIII as an equal volume of fresh plasma. The specific activity after addition of human albumin is in the range of 9 to 22 units/mg protein. KOĀTE also contains naturally occurring von Willebrand factor, which is co-purified as part of the manufacturing process.

The KOĀTE manufacturing process includes two dedicated steps with virus inactivation capacity. The solvent/detergent treatment step has the capacity to inactivate enveloped viruses (such as HIV, HCV, HBV, and WNV). Heat treatment at 80°C for 72 hours has the capacity to inactivate enveloped viruses (such as HIV and HCV) as well as non-enveloped viruses (such as HAV and B19V). The polyethylene glycol (PEG) precipitation/depth filtration step has the capacity to remove both enveloped and non-enveloped viruses. The accumulated virus reduction factors for KOĀTE manufacturing process are presented in Table 2.

		En	veloped \		Non-enveloped Viruses			
	HIV- 1	BVDV	PRV	VSV	WNV	Reo3	HAV	PPV
Model for	HIV- 1/2	HCV	Large enveloped DNA viruses (e.g., herpes virus)	Enveloped RNA viruses		Non- enveloped viruses	HAV	B19V
Global Reduction Factor	≥ 12.0	≥ 11.5	≥ 10.8	≥ 10.9	≥ 5.9*	≥ 9.9	≥ 5.5	4.8
* WNV ina treatment			as evaluate	ed only for	the so	olvent/dete	ergen	it

Table 2: Virus Clearance Capacity (Log_{10}) for the Antihemophilic Factor (Human) Manufacturing Process

Additionally, the manufacturing process was investigated for its capacity to decrease the infectivity of an experimental agent of transmissible spongiform encephalopathy (TSE), considered a model for the variant Creutzfeldt-Jakob disease (vCJD) and Creutzfeldt-Jakob disease (vCJD) agents. The manufacturing process has been shown to decrease TSE infectivity of that experimental model agent (a total of 5.1 log₁₀ reduction), providing reasonable assurance that low levels of vCJD/CJD agent infectivity, if present in the

starting material, would be removed.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

KOĀTE temporarily replaces the missing clotting Factor VIII that is needed for effective hemostasis.

12.2 Pharmacodynamics

Hemophilia A is a bleeding disorder characterized by a deficiency of functional coagulation Factor VIII, resulting in a prolonged plasma clotting time as measured by the activated partial thromboplastin time (aPTT) assay. Treatment with KOĀTE normalizes the aPTT over the effective dosing period.

12.3 Pharmacokinetics

The pharmacokinetics (PK) of KOĀTE were evaluated in a prospective, two-stage clinical trial of 20 previously treated patients (PTPs) with severe hemophilia A. In Stage I, the PK parameters for 19 subjects were based on plasma Factor VIII activity after a single intravenous infusion of 50 IU/kg of KOĀTE. Bioequivalence of the dry heat-treated KOĀTE to the unheated KOĀTE was demonstrated by comparison of C_{max} and the area under the curve, AUC₀₋₄₈ (Table 3). The incremental *in vivo* recovery ten minutes after infusion of dry heat-treated KOĀTE was 1.90% unit/kg (unheated KOĀTE was 1.82% units/kg). Mean biologic half-life was 16.1 hours.

In Stage II of the study, participants received KOĀTE treatments for six months on home therapy with a median of 52 days (range 23 to 94 days). At the end of 6 months, the mean AUC₀₋₄₈ was 1471 ± 237 unit*hour/100 mL, the C_{max} was 99 ± 13 unit/100 mL, and the t_{1/2}was 16 ± 3.9 hours.

Parameter	KOĀTE Dry Heat- treated (mean ± SD)	KOĀTE Unheated (mean ± SD)
AUC ₀₋₄₈ (IU hr/mL))	1432 ±288	1477 ± 343
C _{max} (IU/mL)	103 ± 19	99 ± 20
T _{max} (hr)	0.41 ± 0.26	0.43 ± 0.44
Half life (hr)	16.1 ± 3.2	16.1 ± 5.1

Table 3: PK Parameters of KOĀTE (Stage I of Crossover Trial)

14 CLINICAL STUDIES

The efficacy of KOĀTE for the treatment of bleeding episodes was demonstrated in a 2-

stage, safety, PK and efficacy clinical trial. Stage I was a randomized, single-blind, singledose, crossover, and PK study comparing heat-treated KOĀTE with unheated KOĀTE. Nineteen subjects were randomized and received a single dose of 50 IU/kg of either heated KOĀTE or unheated KOĀTE for PK assessment. Stage II was a 6 month openlabel safety study conducted at two hemophilia centers. Nineteen subjects received KOĀTE, including for on-demand treatment and control of bleeding episodes. The study populations included 15 Caucasians, 3 Hispanic, and 1 Black subject. A total of 306 bleeding episodes were treated, of which 82% were treated with a single infusion of Factor VIII.

15 REFERENCES

- 1. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia 2013;19(1):e1-47.
- 2. Abildgaard CF. Current concepts in the management of hemophilia. Semin Hematol 1975;12(3):223-32.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

KOĀTE is supplied in single-use vials containing 250, 500 or 1,000 IU of Factor VIII activity, packaged with 5 mL or 10 mL of Sterile Water for Injection, one sterile doubleended transfer needle, one sterile filter needle, and one sterile administration set. The actual amount of KOĀTE in IU is stated on each carton and vial label.

Components used in the packaging of KOĀTE are not made with natural rubber latex.

Strength	NDC Number Carton (Kit)
250 IU	76125-250-20, 76125-253-25 or 76125-258-02
500 IU	76125-667-30, 76125-662-50 or 76125-661-02
1,000 IU	76125-672-50, 76125-674-10 or 76125-675-12

Storage and Handling

- Store KOĀTE in its original package to protect it from light.
- Store the KOĀTE package at 2 to 8°C (36 to 46°F). Do not freeze.
- KOĀTE may also be stored at room temperature (up to 25°C or 77°F) for up to 6 months.

- Do not use after the expiration date.
- Use reconstituted KOĀTE immediately or within 3 hours of reconstitution.

17 PATIENT COUNSELING INFORMATION

- Inform patients to immediately report the following early signs and symptoms of hypersensitivity reactions to their healthcare professional: angioedema, chest tightness, hypotension, rash, nausea, vomiting, paresthesia, restlessness, wheezing and dyspnea. [see Warnings and Precautions (5.1)]
- Inform patients that the development of inhibitors to Factor VIII is a possible complication of treatment with KOĀTE. Advise the patients to contact their healthcare provider for further treatment and/or assessment if they experience a lack of clinical response to KOĀTE because this may be a manifestation of an inhibitor. [see Warnings and Precautions (5.2)]
- Inform patients that KOĀTE is made from human plasma and may carry a risk of transmitting infectious agents. While the risk that KOĀTE can transmit an infection has been reduced by screening plasma donors for prior exposure, testing donated plasma, and inactivating or removing certain viruses during manufacturing, patients should report any symptoms that concern them. *[see Warnings and Precautions (5.4)*

Manufactured for: **Kedrion Biopharma Inc**.

400 Kelby Street Fort Lee, NJ 07024

Manufactured by: **Grifols Therapeutics LLC** Research Triangle Park, NC 27709 USA US License No. 1871

3058091

PACKAGE LABEL

NDC 76125-250-20

Koāte[®] Antihemophilic Factor (Human)

250 IU FVIII Range

Solvent/Detergent Treated

Heat-Treated at 80°C

5 mL

Rx only

CONTENTS: One bottle of Koāte 5 mL Sterile Water for Injection, USP One sterile filter needle One sterile double-ended transfer needle One sterile administration set

No Preservative

For Intravenous Administration Only

Sterile — Nonpyrogenic

Date removed from refrigeration_____

WARNING: THIS PRODUCT IS PREPARED FROM LARGE POOLS OF HUMAN PLASMA WHICH MAY CARRY THE RISK OF TRANSMITTING INFECTIOUS AGENTS.

The patient and physician should discuss the risks and benefits of this product.

Dosage and Administration: Read enclosed package insert.

Store refrigerated at 2 to 8°C (36 to 46°F) and no more than 6 months at room temperature (up to 25°C; 77°F) at any time prior to the expiration date. Avoid freezing.

Reconstitute with 5 mL Sterile Water for Injection, USP.

Administer within 3 hours after reconstitution.

This product when reconstituted contains not more than (NMT) 1500 µg/mL polyethylene glycol (PEG), NMT 0.05 M glycine, NMT 25 µg/mL polysorbate 80, NMT 5 µg/g tri-n-butyl phosphate (TNBP), NMT 3 mM calcium, NMT 1 µg/mL aluminum, NMT 0.06 M histidine, and NMT 10 mg/mL Albumin (Human).

If the shrink band is absent or shows any sign of tampering, do not use the product and notify Grifols Therapeutics LLC immediately.

Not Returnable for Credit or Exchange

Manufactured for: **Kedrion Biopharma Inc.** 400 Kelby Street, Fort Lee, NJ 07024

Manufactured by: **Grifols Therapeutics LLC** Research Triangle Park, NC 27709 USA U.S. License No. 1871

Antihemophilic Factor (Human)

Carton: 3054099



NDC 76125-252-21

Koāte[®]

Antihemophilic Factor (Human)

Solvent/Detergent Treated

Heat-Treated at 80°C

Manufactured for: **Kedrion Biopharma Inc.** 400 Kelby Street, Fort Lee, NJ 07024

Manufactured by: **Grifols Therapeutics LLC** Research Triangle Park, NC 27709 USA U.S. License No. 1871

The patient and physician should discuss the risks and benefits of this product.

No Preservative

For Intravenous Administration Only

Sterile—Nonpyrogenic

Reconstitute with 5 mL Sterile Water for Injection, USP.

Store at 2-8°C (36-46°F) and no more than 6 months at room temperature (up to 25°C; 77°F) at any time prior to the expiration date.

Dosage and Administration: Read package insert.

Rx only

Date removed from refrigeration_____

Lot

Exp.

IU

3051798



NDC 76125-667-30

Koāte® Antihemophilic Factor (Human)

500 IU FVIII Range

Solvent/Detergent Treated

Heat-Treated at 80°C

5 mL

Rx only

CONTENTS: One bottle of Koāte 5 mL Sterile Water for Injection, USP One sterile filter needle One sterile double-ended transfer needle One sterile administration set

No Preservative

For Intravenous Administration Only

Sterile — Nonpyrogenic

Date removed from refrigeration____

WARNING: THIS PRODUCT IS PREPARED FROM LARGE POOLS OF HUMAN PLASMA WHICH MAY CARRY THE RISK OF TRANSMITTING INFECTIOUS AGENTS.

The patient and physician should discuss the risks and benefits of this product.

Dosage and Administration: Read enclosed package insert.

Store refrigerated at 2 to 8°C (36 to 46°F) and no more than 6 months at room temperature (up to 25°C; 77°F) at any time prior to the expiration date. Avoid freezing.

Reconstitute with 5 mL Sterile Water for Injection, USP.

Administer within 3 hours after reconstitution.

This product when reconstituted contains not more than (NMT) 1500 μ g/mL polyethylene glycol (PEG), NMT 0.05 M glycine, NMT 25 μ g/mL polysorbate 80, NMT 5 μ g/g tri-n-butyl phosphate (TNBP), NMT 3 mM calcium, NMT 1 μ g/mL aluminum, NMT 0.06 M histidine, and NMT 10 mg/mL Albumin (Human).

If the shrink band is absent or shows any sign of tampering, do not use the product and notify Grifols Therapeutics LLC immediately.

Not Returnable for Credit or Exchange

Manufactured for: **Kedrion Biopharma Inc.** 400 Kelby Street, Fort Lee, NJ 07024

Manufactured by: Grifols Therapeutics LLC Research Triangle Park, NC 27709 USA

U.S. License No. 1871

GTIN XXXXXXXXXXXXXX LOT XXXXXXXXXX EXP DDMMMYYYY SN XXXXXXXXXXXXXXXXX IU XXX

Antihemophilic Factor (Human)

Carton: 3054100



NDC 76125-669-31

Koāte®

Antihemophilic Factor (Human)

Solvent/Detergent Treated

Heat-Treated at 80°C

Manufactured for: **Kedrion Biopharma Inc.** 400 Kelby Street, Fort Lee, NJ 07024 Manufactured by: **Grifols Therapeutics LLC** Research Triangle Park, NC 27709 USA U.S. License No. 1871

The patient and physician should discuss the risks and benefits of this product.

No Preservative

For Intravenous Administration Only

Sterile—Nonpyrogenic

Reconstitute with 5 mL Sterile Water for Injection, USP.

Store at 2-8°C (36-46°F) and no more than 6 months at room temperature (up to 25°C; 77°F) at any time prior to the expiration date.

Dosage and Administration: Read package insert.

Rx only

Date removed from refrigeration_____

Lot

Exp.

IU

3051807



Koāte® Antihemophilic Factor (Human)

1000 IU FVIII Range

Solvent/Detergent Treated

Heat-Treated at 80°C

10 mL

Rx only

CONTENTS: One bottle of Koāte 10 mL Sterile Water for Injection, USP One sterile filter needle One sterile double-ended transfer needle One sterile administration set

No Preservative

For Intravenous Administration Only

Sterile — Nonpyrogenic

Date removed from refrigeration_____

WARNING: THIS PRODUCT IS PREPARED FROM LARGE POOLS OF HUMAN PLASMA WHICH MAY CARRY THE RISK OF TRANSMITTING INFECTIOUS AGENTS.

The patient and physician should discuss the risks and benefits of this product.

Dosage and Administration: Read enclosed package insert.

Store refrigerated at 2 to 8°C (36 to 46°F) and no more than 6 months at room temperature (up to 25°C; 77°F) at any time prior to the expiration date. Avoid freezing.

Reconstitute with 10 mL Sterile Water for Injection, USP.

Administer within 3 hours after reconstitution.

This product when reconstituted contains not more than (NMT) 1500 μ g/mL polyethylene glycol (PEG), NMT 0.05 M glycine, NMT 25 μ g/mL polysorbate 80, NMT 5 μ g/g tri-n-butyl phosphate (TNBP), NMT 3 mM calcium, NMT 1 μ g/mL aluminum, NMT 0.06 M histidine, and NMT 10 mg/mL Albumin (Human).

If the shrink band is absent or shows any sign of tampering, do not use the product and notify Grifols Therapeutics LLC immediately.

Not Returnable for Credit or Exchange

Manufactured for: **Kedrion Biopharma Inc.** 400 Kelby Street, Fort Lee, NJ 07024

Manufactured by: **Grifols Therapeutics LLC** Research Triangle Park, NC 27709 USA

U.S. License No. 1871

Antihemophilic Factor (Human)

Carton: 3054101



NDC 76125-673-51

Koāte®

Antihemophilic Factor (Human)

Solvent/Detergent Treated

Heat-Treated at 80°C

Manufactured for: Kedrion Biopharma Inc. 400 Kelby Street, Fort Lee, NJ 07024

Manufactured by: **Grifols Therapeutics LLC** Research Triangle Park, NC 27709 USA U.S. License No. 1871 The patient and physician should discuss the risks and benefits of this product.

No Preservative

For Intravenous Administration Only

Sterile—Nonpyrogenic

Reconstitute with 10 mL Sterile Water for Injection, USP.

Store at 2-8°C (36-46°F) and no more than 6 months at room temperature (up to 25°C; 77°F) at any time prior to the expiration date.

Dosage and Administration: Read package insert.

Rx only

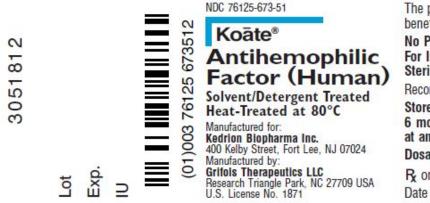
Date removed from refrigeration

Lot

Exp.

IU

3051812



The patient and physician should discuss the risks and benefits of this product.

No Preservative For Intravenous Administration Only Sterile—Nonpyrogenic Reconstitute with 10 mL Sterile Water for Injection, USP. Store at 2–8°C (36–46°F) and no more than 6 months at room temperature (up to 25°C; 77°F) at any time prior to the expiration date.

Dosage and Administration: Read package insert.

R only Date removed from refrigeration

NDC 13533-000-04

3053017

Nonpyrogenic

Single-Dose Container

5 mL

Sterile Water for Injection, USP for reconstitution of accompanying product

Do not use unless clear. No antimicrobial agent or other substance has been added. Do not use for intravascular injection without making approximately isotonic by addition of suitable solute. Discard unused portion.

Rx Only.

Mfd by: **Baxter Healthcare Corporation** Deerfield, IL 60015 USA

Mfd for: **Grifols Therapeutics LLC** Research Triangle Park, NC 27709 USA

07-32-00-0008

Lot Exp





NDC 76297-002-02

Sterile Water for Injection, USP

5 mL Rx Only

For reconstitution of accompanying product

Single-Dose Container, Nonpyrogenic

Do not use unless clear. No antimicrobial agent or other substance has been added. Do not use for intravascular injection without making approximately isotonic by addition of suitable solute. Discard unused portion. Mfd by: Laboratorios Grifols, S.A. Parets del Vallès, Barcelona 08150 Spain

Lot EXP

3057422



NDC 13533-200-05

Sterile Water for Injection, USP 5 mL Rx Only

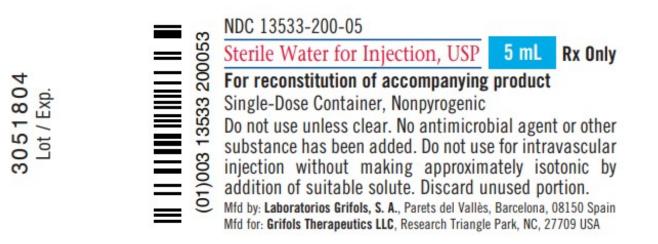
For reconstitution of accompanying product

Single-Dose Container, Nonpyrogenic Do not use unless clear. No antimicrobial agent or other substance has been added. Do not use for intravascular injection without making approximately isotonic by addition of suitable solute. Discard unused portion.

Mfd by: **Laboratorios Grifols, S. A.**, Parets del Vallès, Barcelona, 08150 Spain Mfd for: **Grifols Therapeutics LLC**, Research Triangle Park, NC, 27709 USA

3051804

Lot / Exp.



		·	-) .'t				
antii	nemophii	ic factor (humaı	1) KIT				
Pre	oduct In	formation					
Pro	oduct Typ	e PLAS M	A DERIVATIVE	Item Code (Source)		NDC:76	5125-250
Pa	ckaging						
#	ltem Code		Package Descrip	otion	Market Start Da		Marketing End Date
1 ^N ₂	NDC:76125- 250-20		pe 9: Other Type of Pa /Biological Product)	rt 3 Combination Product			
_							
^	antity o	f Darte					
-	rt #	Package	Quantity	Total P	roduct Qı	lantit	v
Parl		, GLASS	Quantity	5 mL	louuct Qi	antic	y
Par		, GLASS		5 mL			
Pa	rt 1 of	f 2					
КС	DATE						
ant	ihemophi	ilic factor (huma	n) injection, powde	r, lyophilized, for solut	ion		
Pre	oduct In	formation					
Ite	m Code (S	Source)	NDC:76125-252				
Rou	ute of Ad	ministration	INTRAVENOUS				

Active Ingredient/Active Moiety

	Ingr	edient Name		Basis Streng		Strengt
Antihemophilic F a Human - UNII:839M		JNII: 839MOZ74GK) (Antihemophilic		Antihemophil Human	ic Factor	250 [iU] in 5 mL
Inactive Ingre					Chris	
Albumin Human (I		ngredient Name			Stre	ngth
Sodium Chloride						
Histidine (UNII: 4Q						
Calcium Chloride	(UNII: M4I0D6V)	/5M)				
Packaging						
# Item Code	Pa	ckage Description		ing Start ate		eting End Date
1 NDC:76125- 252-21	5 mL in 1 VIAL, Product	GLASS; Type 0: Not a Combination				
Marketing			Mayleat	ing Chart	Marula	atin <i>a</i> Fud
Marketing Category	Арриса	tion Number or Monograph Citation		ing Start ate		eting End Date
Part 2 of 2						
	ATER					
	ATER					
water injection						
water injection Product Infor	rmation	NDC:13533-000				
water injection Product Infor Item Code (Sou	rmation rce)	NDC:13533-000 INTRAVENOUS				
water injection Product Infor Item Code (Sou Route of Admin	r mation rce) istration					
water injection Product Infor Item Code (Sou Route of Admin	rmation rce) istration				Strengt	h
water injection Product Infor Item Code (Sou Route of Admin Inactive Ingre	rmation rce) istration edients Ingu	INTRAVENOUS			Strengt	h
water injection Product Infor Item Code (Sou Route of Admin Inactive Ingre	rmation rce) istration edients Ingu	INTRAVENOUS			Strengt	h
STERILE W water injection Product Infor Item Code (Sou Route of Admin Inactive Ingre Water (UNII: 059Q) Packaging # Item Code	rmation rce) istration edients Ing FOKOOR)	INTRAVENOUS		ing Start ate	Marke	h eting End Date

Marketing I	nformat	ion					
Marketing Category	Applica	tion Number or Mo Citation	onograph		ng Start te	Ma	rketing End Date
BLA	BLA101130			05/20/1999			
Marketing I	nformat	ion					
Marketing Category	Applica	tion Number or Mo Citation	onograph		ng Start te	Ma	rketing End Date
BLA	BLA101130			05/20/1999			
KOATE							
antihemophilic fac	tor (human)) kit					
Product Inform	nation						
Product Type	PLAS MA	DERIVATIVE	ltem Code	(Source)	1	NDC:76	5125-253
				(000100)			
Packaging							
# Item		Package Descrip	otion		Market		Marketing
# Item Code		Package Descrip		on Droduct	Marketi Start Da		Marketing End Date
# Item Code 1 NDC:76125- 1 in 1	l CARTON; Typ , Drug/Device/I	Package Descrip be 9: Other Type of Par Biological Product)		on Product			
# Item Code 1 NDC:76125- 1 in 1	l CARTON; Typ , Drug/Device/I	e 9: Other Type of Par		on Product			
Item Code 1 NDC:76125- 253-25 1 in 1 (e.g.,	, Drug/Device/I	e 9: Other Type of Par		on Product			
Item Code 1 NDC:76125- 253-25 1 in 1 (e.g., Quantity of Pa	, Drug/Device/I	e 9: Other Type of Par Biological Product)				ate	End Date
Item Code 1 NDC:76125- 253-25 1 in 1 (e.g., Quantity of Pa Part # Part 1 1 VIAL, GLA	, Drug/Device/I I rts Package (SS	e 9: Other Type of Par Biological Product)	rt 3 Combinati 5 mL		Start Da	ate	End Date
Item Code 1 NDC:76125- 253-25 1 in 1 (e.g., Quantity of Pa Part # Part #	, Drug/Device/I I rts Package (SS	e 9: Other Type of Par Biological Product)	rt 3 Combinati		Start Da	ate	End Date
Item Code 1 NDC:76125- 253-25 1 in 1 (e.g., Quantity of Pa Part # Part 1 1 VIAL, GLA	, Drug/Device/I I rts Package (SS	e 9: Other Type of Par Biological Product)	rt 3 Combinati 5 mL		Start Da	ate	End Date
Code 1 NDC:76125- 253-25 1 in 1 (e.g., Quantity of Pa Part # Part 1 1 VIAL, GLA	, Drug/Device/I I rts Package (SS	e 9: Other Type of Par Biological Product)	rt 3 Combinati 5 mL		Start Da	ate	End Date
# Item Code 1 NDC:76125- 253-25 1 in 1 (e.g., Quantity of Pa Part # Part 1 1 VIAL, GLA: Part 2 1 VIAL, GLA:	, Drug/Device/I I rts Package (SS	e 9: Other Type of Par Biological Product)	rt 3 Combinati 5 mL		Start Da	ate	End Date
Item Code 1 NDC:76125- 253-25 1 in 1 (e.g., Quantity of Pa Part # Part 1 1 VIAL, GLA Part 2 1 VIAL, GLA Part 1 of 2 KOATE	, Drug/Device/I rts Package (SS SS	e 9: Other Type of Par Biological Product)	rt 3 Combinati 5 mL 5 mL	Total Pr	Start Da	ate	End Date
Item Code 1 NDC:76125- 253-25 1 in 1 (e.g., Quantity of Pa Part # Part 1 1 VIAL, GLA Part 2 1 VIAL, GLA Part 1 of 2 KOATE	, Drug/Device/I rts Package (SS SS	e 9: Other Type of Par Biological Product)	rt 3 Combinati 5 mL 5 mL	Total Pr	Start Da	ate	End Date
# Item Code 1 NDC:76125- 253-25 1 in 1 (e.g., Quantity of Pa Part # Part 1 1 VIAL, GLA: Part 2 1 VIAL, GLA: Part 1 of 2 KOATE antihemophilic far	, Drug/Device/I Irts Package (SS SS	e 9: Other Type of Par Biological Product)	rt 3 Combinati 5 mL 5 mL	Total Pr	Start Da	ate	End Date
Item Code 1 NDC:76125- 253-25 1 in 1 (e.g., Quantity of Pa Part # Part 1 1 VIAL, GLA Part 2 1 VIAL, GLA Part 1 of 2 KOATE	, Drug/Device/I Irts Package (SS SS	e 9: Other Type of Par Biological Product)	rt 3 Combinati 5 mL 5 mL	Total Pr	Start Da	ate	End Date
# Item Code 1 NDC:76125- 253-25 1 in 1 (e.g., Quantity of Pa Part # Part 1 1 VIAL, GLA: Part 2 1 VIAL, GLA: Part 1 1 VIAL, GLA: Part 2 1 VIAL, GLA: Part 1 1 VIAL, GLA: Part 2 1 VIAL, GLA: Part 1 1 VIAL, GLA:	, Drug/Device/I Package (SS SS ctor (humar nation	e 9: Other Type of Par Biological Product)	rt 3 Combinati 5 mL 5 mL	Total Pr	Start Da	ate	End Date

	Ingr	edient Name			asis of rength	Strength
		JNII: 839MOZ74GK) (Antihemophilic I	actor	Antihemo	ophilic Factor	250 [iU]
Human - UNII:839M0	OZ 74GK)			Human		in 5 mL
Inactive Ingre		n un die ut Neuro			Church	+ l-
Albumin Human (U		ngredient Name			Strei	ngtn
Sodium Chloride						
Histidine (UNII: 4Q		,				
Calcium Chloride	(UNII: M410D6V)	/5M)				
Packaging						
# Item Code	Pa	ckage Description		ting Sta Date		eting End Date
1 NDC:76125- 252-21	5 mL in 1 VIAL, Product	GLASS; Type 0: Not a Combination				
Marketing	Informat	ion				
			Marka	ting Cto	wh Manula	ting Fud
Marketing Category	Аррисат	tion Number or Monograph Citation		ting Sta Date		eting End Date
BLA	BLA101130		05/20/199	99		
Part 2 of 2						
STERILE W	ATER					
water injection						
Product Infor	mation					
Item Code (Sou	rce)	NDC:13533-200				
Route of Admini		INTRAVENOUS				
Inactive Ingre	dients					
mactive mgre		edient Name			Strengt	h
Water (UNII: 059QF	-				Sticiligt	•
Packaging						
# Item Code	Pa	ckage Description		ting Sta Date		eting End Date
• NDC:13533-	5 mL in 1 VIAL,	GLASS; Type 0: Not a Combination				

1 200-05	Product						
Marketin	g Informat	ion					
Marketin Category		tion Number or Mo Citation	onograph		ng Start Ite	Mar	keting End Date
BLA	BLA101130			05/20/1999			
Markotin	g Informat	ion					
Marketin	-	tion Number or Mo	nograph	Markoti	ng Start	Mar	keting End
Category		Citation	nograph		ite	Мат	Date
BLA	BLA101130			05/20/1999			
ΚΟΑΤΕ							
	c factor (human)) kit					
Product Inf	ormation						
Product Type	PLAS MA	DERIVATIVE	Item Code	(Source)	1	NDC:761	25-258
Packaging							
# Item Code		Package Descrip	otion		Marketi Start Da		Marketing End Date
	1 in 1 CARTON; Typ (e.g., Drug/Device/I	e 9: Other Type of Par Biological Product)	rt 3 Combinatio	on Product			
250 02	(e.g., brag, bettee,						
.							
Quantity of							
Part # Part 1 1 VIAL,	Package C	Quantity	5 ml	Total Pi	roduct Qu	antity	
Part 2 1 VIAL,			5 mL				
Part 1 of	2						
ΚΟΑΤΕ							
-	ic factor (humar) injection, powde	r. lvophilized	l. for soluti	on		
		, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,					
Product Inf	ormation						
ltem Code (S	ource)	NDC:76125-252					
Route of Adn		INTRAVENOUS					

	Ingr	edient Name		Basis Streng		Strength
Antihemophilic F Human - UNII:839M		JNII: 839MOZ74GK) (Antihemophilic		Antihemophili Human		250 [iU] in 5 mL
nactive Ingr	edients					
	I	ngredient Name			Stre	ngth
Albumin Human ((UNII: ZIF514RVZ	R)				
Sodium Chloride	(UNII: 451W47IQ	8X)				
Histidine (UNII: 40	QD397987E)					
Calcium Chloride	≥ (UNII: M4I0D6∨	/5M)				
Packaging						
# Item Code	Pa	ckage Description		ing Start ate		eting End Date
1 NDC:76125- 252-21	5 mL in 1 VIAL, Product	GLASS; Type 0: Not a Combination				
	_					
Marketing						
Marketing Category	Applica	tion Number or Monograph Citation		ing Start ate		eting End Date
BLA	BLA101130		05/20/1999	9		
Part 2 of 2	2					
STERILE W						
STERILE W water solution	ATER					
STERILE W	ATER					
STERILE W water solution	ATER	NDC:76297-002				
STERILE W water solution Product Info	ATER rmation urce)	NDC:76297-002 INTRAVENOUS				
STERILE W water solution Product Info	ATER rmation urce)					
STERILE W water solution Product Info	ATER rmation urce) histration	INTRAVENOUS				
STERILE W water solution Product Info Item Code (Sou Route of Admin	ATER rmation urce) histration	INTRAVENOUS Moiety	Basis c	of Strength		Strength
STERILE W water solution Product Info Item Code (Sou Route of Admin Active Ingred	ATER rmation (rce) histration lient/Active Ingredie	INTRAVENOUS Moiety nt Name	Basis c Water	of Strength		Strength _ in 1 mL
STERILE W water solution Product Info Item Code (Sou Route of Admin	ATER rmation (rce) histration lient/Active Ingredie	INTRAVENOUS Moiety nt Name		of Strength		-

1 NDC:76297- 002-02	5 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
Marketing	Information		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		05/20/1999	
Marketing	Information		
Marketing Marketing Category	Information Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Marketing Category	Application Number or Monograph	-	-
Marketing Category	Application Number or Monograph Citation	Date	-
Marketing Category BLA	Application Number or Monograph Citation	Date	-
Marketing Category BLA KOATE	Application Number or Monograph Citation BLA101130	Date	-
Marketing Category BLA KOATE	Application Number or Monograph Citation	Date	-
Marketing Category BLA KOATE	Application Number or Monograph Citation BLA101130	Date	-

Product Type

PLAS MA DERIVATIVE

IVE	Item Code (Source)	NDC:76125-667

P	ackaging				
#	ltem Code	Package Descrip	tion	Marketing Start Date	Marketing End Date
1	NDC:76125- 667-30	1 in 1 CARTON; Type 9: Other Type of Par (e.g., Drug/Device/Biological Product)	t 3 Combination Product		
Q	uantity o	f Parts			
Pa	art #	Package Quantity	Total P	roduct Ouantit	v

Pa	rt #	Package Quantity	Total Product Quantity
Par	t 1	1 VIAL, GLASS	5 mL
Par	t 2	1 VIAL, GLASS	5 mL

Part 1 of 2

KOATE

antihemophilic factor (human) injection, powder, lyophilized, for solution

Product Information	
Item Code (Source)	NDC:76125-669
Route of Administration	INTRAVENOUS

	Ingr	edient Name			is of ngth	Strength
Antihemophilic F Human - UNII:839N		JNII: 839MOZ74GK) (Antihemophilic	Factor	Antihemop Human	hilic Factor	500 [iU] in 5 mL
Inactive Ingr						
		ngredient Name			Stre	ngth
Albumin Human Sodium Chloride						
Histidine (UNII: 40		o^)				
Calcium Chloride		/5M)				
Packaging			Markot	ing Starl	Mark	ating End
# Item Code	Pa	ckage Description		ate		eting End Date
1 NDC:76125-		GLASS; Type 0: Not a Combination				
669-31	Product					
		-				
Marketing	Informat	ion				
Marketing Category	Applica	tion Number or Monograph Citation		ting Start Date		eting End Date
Caledory		CILATION				Date
• •	BI 4101130		_			
• •	BLA101130		05/20/199			
• •	BLA101130		_			
BLA			_			
			_			
BLA	2		_			
Part 2 of 2 STERILE W	2		_			
Part 2 of 2 STERILE W	2		_			
Part 2 of 2 STERILE W	2		_			
Part 2 of 2 STERILE W water injection	2 /ATER		_			
BLA Part 2 of 2 STERILE W water injection Product Info	2 /ATER ormation		_			
BLA Part 2 of 2 STERILE W water injection Product Info Item Code (Sou	2 /ATER ormation urce)	NDC:13533-000	_			
BLA Part 2 of 2 STERILE W water injection Product Info	2 /ATER ormation urce)		_			
BLA Part 2 of 2 STERILE W water injection Product Info Item Code (Sou	2 /ATER ormation urce)	NDC:13533-000	_			
BLA Part 2 of 2 STERILE W water injection Product Info Item Code (Sou Route of Admir	2 /ATER ormation urce) nistration	NDC:13533-000	_			
BLA Part 2 of 2 STERILE W water injection Product Info Item Code (Sou Route of Admir	2 /ATER ormation urce) nistration	NDC:13533-000 INTRAVENOUS	_			
BLA Part 2 of 2 STERILE W water injection Product Info Item Code (Sou Route of Admin	2 /ATER ormation urce) nistration redients	NDC:13533-000	_		Strengt	h
BLA Part 2 of 2 STERILE W water injection Product Info Item Code (Sou Route of Admir	2 /ATER ormation urce) nistration redients	NDC:13533-000 INTRAVENOUS	_			h
BLA Part 2 of 2 STERILE W water injection Product Info Item Code (Sou Route of Admin	2 /ATER ormation urce) nistration redients	NDC:13533-000 INTRAVENOUS	_			h
BLA Part 2 of 2 STERILE W water injection Product Info Item Code (Sou Route of Admin	2 /ATER ormation urce) nistration redients	NDC:13533-000 INTRAVENOUS	_			h

# Item Code	Pa	ckage Descriptio	on	магкеті Da	ng start Ite	Marketing End Date
1 NDC:13533- 000-04	5 mL in 1 VIAL, Product	GLASS; Type 0: Not a	Combination			
Marketing	Informat	ion				
Marketing		tion Number or Mo	onograph	Marketi	ng Start	Marketing End
Category	Applica	Citation	Shograph		ate	Date
BLA	BLA101130			05/20/1999		
Marketing	Informat	ion				
Marketing Category	Applica	tion Number or Mo Citation	onograph		ng Start ate	Marketing End Date
BLA	BLA101130			05/20/1999		
ΚΟΑΤΕ						
antihemophilic f	actor (human) kit				
Product Info	rmation					
Product Type	PLAS MA	DERIVATIVE	ltem Code	(Source)	٦	NDC:76125-662
Packaging						
# Item Code		Package Descri	otion		Marketi Start Da	
		e 9: Other Type of Pa Biological Product)	rt 3 Combinati	on Product		
Quantity of F	Parts					
Part #	Package (Quantity		Total P	roduct Qu	antity
Part 1 1 VIAL, G			5 mL			
Part 2 1 VIAL, G	LASS		5 mL			
Part 1 of 2	-					
ΚΟΑΤΕ						
antihemophilic	factor (humar	ı) injection, powde	r, lyophilized	d, for solut	ion	
Product Info	rmation					
Item Code (Sou	urce)	NDC:76125-669				
Route of Admir		INTRAVENOUS				
Route of Admir	istration	INTRAVENOUS				

Active Ingredie	ent/Active	Moiety				
	Ingr	edient Name			is of ngth	Strength
Antihemophilic Fac Human - UNII:839MO2		JNII: 839MOZ 74GK) (Antihemophilic	Factor	Antihemop Human	hilic Factor	500 [iU] in 5 mL
Inactive Ingred	lients					
3		ngredient Name			Stre	ngth
Albumin Human (UN		-				
Sodium Chloride (U	JNII: 451W47IQ	8X)				
Histidine (UNII: 4QD	397987E)					
Calcium Chloride (UNII: M410D6V\	/5M)				
Packaging						
# Item Code	Ра	ckage Description		ting Start ate		eting End Date
	5 mL in 1 VIAL, Product	GLASS; Type 0: Not a Combination				
Markating	nformat					
Marketing I						
Marketing Category	Applicat	tion Number or Monograph Citation		ting Start Date		eting End Date
BLA	BLA101130		05/20/199	9		
Part 2 of 2						
STERILE WA	TER					
water injection						
Product Inform	nation					
Item Code (Sourc	ce)	NDC:13533-200				
Route of Adminis	tration	INTRAVENOUS				
Inactive Ingred	lients					
		edient Name			Strengt	h
Water (UNII: 059QF0	KOOR)					
Packaging						

#	Item Code	Pa	ickage Descriptio	n	Marketii Da			ting End ate
	NDC:13533- 200-05	5 mL in 1 VIAL, Product	GLASS; Type 0: Not a	Combination				
			•					
M		Informat				.		
	Marketing Category	Applica	tion Number or Mo Citation	nograph		ng Start Ite		ting End ate
BL/	4	BLA101130			05/20/1999			
Μ	arketing	l Informat	ion					
	- Marketing Category	Applica	tion Number or Mo Citation	nograph		ng Start Ite		ting End ate
BL/		BLA101130			05/20/1999			
K	DATE							
		factor (human) kit					
			,					
Pı	roduct Info	ormation						
Pr	oduct Type	PLAS MA	DERIVATIVE	ltem Code	(Source)	N	DC:76125	-661
Pa	ackaging							
#	ltem Code		Package Descrip	tion		Marketiı Start Da		arketing nd Date
1		in 1 CARTON; Typ	be 9: Other Type of Par	rt 3 Combinati	on Product	Start Da	te E	na Date
			Biological Product)					
	uantity of							
_	nrt #	Package (Quantity	E mol	Total Pr	roduct Qua	antity	
	rt 1 1 VIAL, 0 rt 2 1 VIAL, 0			5 mL 5 mL				
	, ,							
Pa	art 1 of 2	2						
	ΟΑΤΕ							
an	tihemophilic	factor (humar	n) injection, powde	r, lyophilized	l, for soluti	on		
Р	roduct Info	ormation						
Ite	em Code (So	urce)	NDC:76125-669					

Active Ingred	ient/Active	Moiety				
	Ingr	edient Name			sis of ength	Strength
		JNII: 839MOZ74GK) (Antihemophilic	Factor	Antihemop	ohilic Factor	500 [iU]
Human - UNII:839M	OZ 74GK)			Human		in 5 mL
Inactive Ingre		unus dia ut Nama			Chura	
Albumin Human (ngredient Name			Stre	ngth
Sodium Chloride						
Histidine (UNII: 4Q						
Calcium Chloride	(UNII: M4I0D6V)	/5M)				
Packaging						
# Item Code	Pa	ckage Description		ting Star ate		eting End Date
1 NDC:76125- 669-31	5 mL in 1 VIAL, Product	GLASS; Type 0: Not a Combination				
NA I I I		-				
Marketing						
Marketing Category	Applicat	tion Number or Monograph Citation		ting Star Date		eting End Date
BLA	BLA101130		05/20/199	9		
Part 2 of 2						
STERILE W	ATER					
water solution						
Product Infor	mation					
ltem Code (Sou	rce)	NDC:76297-002				
Route of Admin	istration	INTRAVENOUS				
Active Ingred	ient/Active	Moiety				
	Ingredie	nt Name	Basis	of Streng	gth S	Strength
Water (UNII: 059Q	F0KO0R) (Water	- UNII:059QF0KO0R)	Water		1 m	L in 1 mL

Packa	aging										
# Itei	m Code		Pac	kage I	Descripti	on		ing Start ate	Ма	rketing Date	End
NDC: 002-0	76297- 02	5 mL Produ		GLASS; T	ype 0: Not	a Combination					
Mark	keting	Info	ormati	on							
	arketing ategory		Applicati		nber or M tation	lonograph		ing Start ate	Ma	rketing Date	End
Unappro other	oved drug						05/20/1999)			
Mark	keting	Info	ormatio	on							
	arketing ategory		Applicati		nber or M tation	lonograph		ing Start ate	Ma	rketing Date	End
BLA		BL	A101130				05/20/1999)			
ntihen	nophilic f		human)	kit							
ntihen Produ	- —				Æ	ltem Code	(Source)		NDC:76	125-672	
Produ Produ Produ Packa	nophilic f uct Info ct Type aging		ion		/Ε	ltem Code	(Source)				
Produ Produ Produ Packa # Ito	aging em ode 76125- 1 i	ormati in 1 CAP	ON PLAS MA D I TON; Type	Packag 9: Othe	J e Descri r Type of Pa			Market Start Da	ing	125-672 Marke End I	
Produ Produ Packa # Ito Cc	aging em ode 76125- 1 i	ormati in 1 CAP	ion Plasma d	Packag 9: Othe	J e Descri r Type of Pa	iption		Market	ing	Marke	
Produ Produ Packa # Ita Co 1 NDC: 672-5	aging em ode 76125- 1 i	in 1 CAR .g., Drug	ON PLAS MA D I TON; Type	Packag 9: Othe	J e Descri r Type of Pa	iption		Market	ing	Marke	
Produ Produ Packa # Ito Cc 1 NDC: 672-5 Quant Part #	aging em ode 76125- 1 i 50 (e.	in 1 CAR .g., Drug Parts Pac	ON PLAS MA D I TON; Type	Packag 9: Other ological	Je Descri r Type of Pa Product)	i ption art 3 Combinat	on Product	Market	ing ate	Marke End I	
Produce Produce Packa # Ito Co 1 NDC: 672-5	aging em ode 76125- 1 i 50 1 i (e.	in 1 CAR .g., Drug Parts Pac GLASS	ion PLAS MA D I I TON; Type g/Device/Bi	Packag 9: Other ological	Je Descri r Type of Pa Product)	iption	on Product	Market Start Da	ing ate	Marke End I	
Produ Produ Packa # It Cc 1 NDC: 672-5 Quant Part # Part 1	aging em ode 76125- 1 i 50 1 i tity of F 1 VIAL, G	in 1 CAR .g., Drug Parts Pac GLASS	ion PLAS MA D I I TON; Type g/Device/Bi	Packag 9: Other ological	Je Descri r Type of Pa Product)	iption art 3 Combinat 10 mL	on Product	Market Start Da	ing ate	Marke End I	
Produce Produce Packa # Itc Cc 1 NDC: 672-5 Quant Part 1 Part 1 Part 2	aging em ode 76125- 1 i 50 1 i tity of F 1 VIAL, G	in 1 CAR .g., Drug Parts Pac SLASS SLASS	ion PLAS MA D I I TON; Type g/Device/Bi	Packag 9: Other ological	Je Descri r Type of Pa Product)	iption art 3 Combinat 10 mL	on Product	Market Start Da	ing ate	Marke End I	
Produce Produce Packa # Itc Cc 1 NDC: 672-5 Quant Part 1 Part 1 Part 2	tity of F 1 VIAL, G	in 1 CAR .g., Drug Parts Pac SLASS SLASS	ion PLAS MA D I I TON; Type g/Device/Bi	Packag 9: Other ological	Je Descri r Type of Pa Product)	iption art 3 Combinat 10 mL	on Product	Market Start Da	ing ate	Marke End I	

Product Information

Item Code (Sour	rce)	NDC:76125-673				
Route of Admini	stration	INTRAVENOUS				
Active Ingredi	ent/Active	Moiety				
	Ingro	edient Name		Basis o Strengt		Strength
Antihemophilic Fa Human - UNII:839M0		JNII: 839MOZ74GK) (Antihemophilic	Factor	Antihemophilic Human	Factor	1000 [iU] in 10 mL
	diauta					
Inactive Ingre					.	
		ngredient Name			Stre	ength
Albumin Human (L						
Sodium Chloride (8X)				
Histidine (UNII: 4Q		(514)				
Calcium Chloride	(UNII: M410D6V	/5M)				
Packaging						
# Item Code	Pa	ckage Description		eting Start Date	Mark	eting End Date
	10 mL in 1 VIAL Combination Pr	., GLASS; Type 0: Not a oduct				
Marketing Marketing		tion Number or Monograph		eting Start	Mar	keting End
Category		Citation		Date		Date
BLA	BLA101130		05/20/19	99		
Part 2 of 2						
STERILE W	ATER					
water injection						
water injection						
Product Infor	mation					
water injection Product Infor Item Code (Sour		NDC:13533-000				
Product Infor Item Code (Sour	rce)	NDC:13533-000 INTRAVENOUS				
Product Infor	rce)					
Product Infor Item Code (Sour Route of Admini	rce) stration					
Product Infor Item Code (Sour Route of Admini	rce) stration dients	INTRAVENOUS			Strong	th
Product Infor Item Code (Sour Route of Admini	rce) stration dients Inge			5	Streng	th
Product Infor Item Code (Sour Route of Admini	rce) stration dients Inge	INTRAVENOUS			Streng	th

Pā	ackaging						
#	ltem Code	Package Descript	ion	Marketin Dat		Ма	rketing End Date
	NDC:13533- 000-05	10 mL in 1 VIAL, GLASS; Type 0: No Combination Product	ot a				
Μ	arketing	Information					
	- Marketing Category	Application Number or N Citation	Monograph	Marketin Dat		Ma	arketing End Date
3L		BLA101130		05/20/1999			
M	arketing	Information					
	Marketing Category	Application Number or N Citation	Monograph	Marketin Dat		Ma	arketing End Date
BL	4	BLA101130		05/20/1999			
nt Pi	roduct Info						
nt Pi	ihemophilic fa		ltem Code	(Source)	N	NDC:76	5125-674
nt Pi Pr	ihemophilic fa	rmation	ltem Code	(Source)	Ν	NDC:76	5125-674
Pi Pr Pa	ihemophilic fa roduct Infoi oduct Type	rmation		(Source)	Marketi Start Da	ng	Marketing
Pi Pr Pa #	roduct Infor roduct Type ackaging Item Code NDC:76125- 1 ir	rmation PLAS MA DERIVATIVE	iption		Marketi	ng	Marketing
Pi Pr Pa #	roduct Infor oduct Type ackaging Item Code NDC:76125- 1 ir	rmation PLAS MA DERIVATIVE Package Desci n 1 CARTON; Type 9: Other Type of F	iption		Marketi	ng	Marketing
Pr Pr 1	roduct Infor oduct Type ackaging Item Code NDC:76125- 1 ir	rmation PLAS MA DERIVATIVE Package Desci h 1 CARTON; Type 9: Other Type of F g., Drug/Device/Biological Product)	iption		Marketi	ng	Marketing
Pr Pr Pa # 1	ihemophilic fa roduct Infor oduct Type ackaging ltem Code NDC:76125- 674-10 1 ir (e.g	PLAS MA DERIVATIVE PLAS MA DERIVATIVE Package Descu n 1 CARTON; Type 9: Other Type of F g., Drug/Device/Biological Product) Parts Package Quantity	ription Part 3 Combinat		Marketi Start Da	ng ite	Marketing End Date
Pr Pr Pa Qu Pa	ihemophilic fa roduct Infor oduct Type ackaging Item Code NDC:76125- 674-10 I ir (e.g uantity of P art # rt 1 1 VIAL, GL	PLAS MA DERIVATIVE PLAS MA DERIVATIVE Package Descu a 1 CARTON; Type 9: Other Type of F g., Drug/Device/Biological Product) Package Quantity ASS	Part 3 Combinat	ion Product	Marketi Start Da	ng ite	Marketing End Date
Pr Pr Pa Qu Pa	ihemophilic fa roduct Infor oduct Type ackaging ltem Code NDC:76125- 674-10 1 ir (e.g	PLAS MA DERIVATIVE PLAS MA DERIVATIVE Package Descu a 1 CARTON; Type 9: Other Type of F g., Drug/Device/Biological Product) Package Quantity ASS	ription Part 3 Combinat	ion Product	Marketi Start Da	ng ite	Marketing End Date
Pr Pr Pa Pa	cihemophilic fa roduct Infor oduct Type ackaging Item Code NDC:76125- 674-10 1 ir (e.g uantity of P ort # rt 1 1 VIAL, GL rt 2 1 VIAL, GL	PLAS MA DERIVATIVE PLAS MA DERIVATIVE Package Descu a 1 CARTON; Type 9: Other Type of F g., Drug/Device/Biological Product) Parts Package Quantity ASS ASS	Part 3 Combinat	ion Product	Marketi Start Da	ng ite	Marketing End Date
Pr Pr Pr Pr Pr Pr Pr Pr Pr Pr	ihemophilic fa roduct Infor oduct Type ackaging Item Code NDC:76125- 674-10 I ir (e.g uantity of P art # rt 1 1 VIAL, GL	PLAS MA DERIVATIVE PLAS MA DERIVATIVE Package Descu a 1 CARTON; Type 9: Other Type of F g., Drug/Device/Biological Product) Parts Package Quantity ASS ASS	Part 3 Combinat	ion Product	Marketi Start Da	ng ite	Marketing End Date

Product Info						
	rmation					
ltem Code (Sou	Item Code (Source) NDC:76125-673					
Route of Administration INTRAVENOUS						
Active Ingred	lient/Active	Moiety				
	Ingre	edient Name			is of ength	Strength
		UNII: 839MOZ74GK) (Antihemophilic	Factor	Antihemop	ohilic Factor	1000 [iU]
Human - UNII:839M	IOZ /4GK)			Human		in 10 mL
Inactive Ingre	edients					
indenie ingr		Ingredient Name			Str	ength
Albumin Human (•				
Sodium Chloride	(UNII: 451W47IQ	8X)				
Histidine (UNII: 40						
Calcium Chloride	e (UNII: M4I0D6V	V5M)				
Packaging			-	_		
# Item Code	Pa	ckage Description		eting Sta Date	rt Mar	keting Enc Date
1 NDC:76125- 673-51	10 mL in 1 VIAL Combination Pr	., GLASS; Type 0: Not a				
073-31		ouuct				
Marketing	Informat	ion				
Marketing	Applica	tion Number or Monograph	Marke	eting Sta	rt Mar	keting End
Category		tion Number or Monograph Citation		Date	rt Mar	keting End Date
Category	Applica BLA101130		Marko 05/20/19	Date	rt Mar	
Category				Date	rt Mar	
Category	BLA101130			Date	rt Mar	
Category BLA Part 2 of 2	BLA101130			Date	rt Mar	
Category BLA Part 2 of 2 STERILE W	BLA101130			Date	rt Mar	keting End Date
Category BLA Part 2 of 2	BLA101130			Date	rt Mar	
Category BLA Part 2 of 2 STERILE W water injection	BLA101130			Date	rt Mar	
Category BLA Part 2 of 2 STERILE W water injection Product Infor	BLA101130	Citation		Date	rt Mar	
Category BLA Part 2 of 2 STERILE W water injection Product Infor Item Code (Sou	BLA101130	Citation Citation		Date	rt Mar	
Category BLA Part 2 of 2 STERILE W water injection Product Infor	BLA101130	Citation		Date	rt Mar	
Category BLA Part 2 of 2 STERILE W water injection Product Infoi Item Code (Sou Route of Admin	BLA101130	Citation Citation		Date	rt Mar	
Category BLA Part 2 of 2 STERILE W water injection Product Infor Item Code (Sou	BLA101130 BLA101130	Citation Citation		Date	rt Mar	Date

Packaging					
# Item Code	Package Descriptio		Marketing St Date	art Ma	arketing End Date
	10 mL in 1 VIAL, GLASS; Type 0: Not Combination Product	a			
Marketing	Information				
Marketing Category	Application Number or Mo Citation	onograph	Marketing St Date	art M	arketing End Date
BLA	BLA101130		05/20/1999		
Marketing	Information				
Marketing Category	Application Number or Mo Citation	onograph	Marketing St Date	art M	arketing End Date
BLA	BLA101130		05/20/1999		
	mation PLAS MA DERIVATIVE	ltom Code	(60,000)	NDC.7	6125-675
Product Type	PLASMA DERIVATIVE	Item Code	(Source)	NDC: /	0125-075
Packaging					
# Item Code	Package Descrip	ption		rketing rt Date	Marketing End Date
	1 CARTON; Type 9: Other Type of Pa ., Drug/Device/Biological Product)	rt 3 Combinatio	on Product		
075 12 (e.g					
· · · · ·	arts				
Quantity of Pa Part #	Package Quantity		Total Produc	t Quanti:	ty
Quantity of Pa Part # Part 1 1 VIAL, GLA	Package Quantity	10 mL	Total Produc	t Quanti:	ty
Quantity of Pa Part #	Package Quantity	10 mL 10 mL	Total Produc	t Quanti:	ty
Quantity of Pa Part # Part 1 1 VIAL, GLA Part 2 1 VIAL, GLA	Package Quantity	-	Total Produc	t Quanti:	ty
Quantity of Pa Part # Part 1 1 VIAL, GL/ Part 2 1 VIAL, GL/ Part 1 of 2	Package Quantity	-	Total Produc	t Quanti	ty
Quantity of Pa Part # Part 1 1 VIAL, GLA Part 2 1 VIAL, GLA Part 1 of 2 KOATE	Package Quantity	10 mL		t Quanti:	ty

	rmation	NDC-76125 672				
	em Code (Source) NDC:76125-673 oute of Administration INTRAVENOUS					
Route of Admir	listration	INTRAVENOUS				
Active Ingred	lient/Active	Moiety				
	Ingro	edient Name			sis of ength	Strength
Antihemophilic F Human - UNII:839M		JNII: 839MOZ74GK) (Antihemophilic	Factor		ohilic Factor	1000 [iU] in 10 mL
Inactive Ingr	edients					
	I	ngredient Name			Str	ength
Albumin Human (
Sodium Chloride		8X)				
Histidine (UNII: 40 Calcium Chloride		/5M)				
		, , , , , , , , , , , , , , , , , , ,				
Packaging						
# Item Code	Pa	ckage Description		eting Sta Date	rt Marl	keting End Date
NDC:76125- 673-51	10 mL in 1 VIAL Combination Pr	., GLASS; Type 0: Not a roduct				
Marketing	Informat	ion				
Marketing Category	Applica	tion Number or Monograph Citation	Mark	eting Sta Date	rt Mar	keting End Date
BLA	BLA101130		05/20/19	99		
Part 2 of 2						
STERILE W	ATER					
Part 2 of 2 STERILE W water solution	ATER					
STERILE W water solution						
STERILE W water solution Product Info	rmation					
STERILE W water solution Product Info	rmation	NDC:76297-002				
STERILE W	rmation arce)	NDC:76297-002 INTRAVENOUS				
STERILE W water solution Product Info Item Code (Sou	rmation urce) histration	INTRAVENOUS				

vatei	r (UNII: 059QI	F0KO0R) (Water - UNII:059QF0KO0R)	Water	1 mL in 1 mL
Pack	caging			
# Ito	em Code	Package Description	Marketing Start Date	Marketing End Date
	C:76297- 2-12	10 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
Mar	rketing	Information		
М	larketing	Application Number or Monograph	Marketing Start	Marketing End
	Category	Citation	Date	Date
C Unapp		Citation	Date 05/20/1999	Date
C	Category	Citation		Date
C Unapp other	Category proved drug	Citation		Date
C Unapp other Mar Mar	Category proved drug			Date Marketing End Date

Labeler - KEDRION BIOPHARMA, INC. (078622209)

Establishment							
Name	Address	ID/FEI	Business Operations				
GRIFOLS THERAPEUTICS LLC		611019113	manufacture(76125-250, 76125-252, 76125-661, 76125-667, 76125-672, 76125- 675, 76125-253, 76125-258, 76125-669, 76125-662, 76125-673, 76125-674)				

Establishment						
Name	Address	ID/FEI	Business Operations			
LABORATORIOS GRIFOLS SA		463719725	manufacture(76297-002)			

Revised: 12/2023

KEDRION BIOPHARMA, INC.