DEHYDRATED ALCOHOL- alcohol injection, solution
BPI Labs, LLC

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

ABLYSINOL (dehydrated alcohol) injection, for cardiac septal branch intra-arterial use

Initial U.S. Approval: 1946

INDICATIONS AND USAGE

ABLYSINOL is an ablative agent indicated to induce controlled cardiac septal infarction to improve exercise capacity in adults with symptomatic hypertrophic obstructive cardiomyopathy who are not candidates for surgical myectomy. (1)

DOSAGE AND ADMINISTRATION

- Inject small volumes over 1 to 2 minutes percutaneously into septal arterial branches, using the minimal dose necessary to achieve the desired reduction in peak left ventricular outflow tract pressure gradient. (2.1)
- In most situations, a dose of 1 mL to 2 mL is sufficient. The maximum dose that should be used in a single procedure is 5 mL. (2.1)

DOSAGE FORMS AND STRENGTHS

- Injection: 1 mL or 5 mL of ethyl alcohol ≥ 99% by volume as a clear, colorless liquid in a single-dose glass ampule. (3)
- Injection: 5 mL of ethyl alcohol ≥ 99% by volume as a clear, colorless liquid in a single-dose glass vial. (3)

CONTRAINDICATIONS

- None (4)

WARNINGS AND PRECAUTIONS

- Transient heart block: Transient heart block is common at the time of injection. A temporary pacing wire is routinely inserted to mitigate transient heart block. (5.1)
- Persistent heart block: Approximately 10% of complete heart block events become permanent and require placement of a permanent pacemaker. (5.1)
- Remove the temporary pacemaker lead if no episode of high-degree atrioventricular block occurs. (5.1)
- Monitor the patient for heart failure, chest pain, and arrhythmias several days after the procedure. (5.1, 5.2, 5.3)

ADVERSE REACTIONS

Adverse reactions include arrhythmias, including ventricular tachycardia and/or ventricular fibrillation. (6)
To report SUSPECTED ADVERSE REACTIONS, contact BPI Labs, LLC at (727) 471-0850 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

USE IN SPECIFIC POPULATIONS

- ABLYSINOL is not recommended during pregnancy. Maternal use is not expected to result in fetal exposure to the drug. (8.1)
- The rate of heart blocks and dysrhythmia increased with age. (8.5)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 1/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

ABLYSINOL ® is indicated to induce controlled cardiac septal infarction to improve exercise capacity in adults with symptomatic hypertrophic obstructive cardiomyopathy who are not candidates for surgical myectomy.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

Use the minimum dose necessary to achieve the desired reduction in peak left ventricular outflow tract pressure gradient. Inject small volumes over 1 to 2 minutes percutaneously into septal arterial branches, guided by assessment of the gradient. In most situations, a dose of 1 mL to 2 mL is sufficient. The maximum dose of ABLYSINOL that should be used in a single procedure is 5 mL.

2.2 Administration

ABLYSINOL should only be administered under the supervision of a qualified interventional cardiologist experienced in the percutaneous transluminal septal myocardial ablation procedure.

Inspect visually for particulate matter and discoloration prior to administration. ABLYSINOL should appear as a clear, colorless solution.

3 DOSAGE FORMS AND STRENGTHS

Injection: 1 mL or 5 mL of ethyl alcohol ≥ 99% by volume as a clear, colorless liquid in a single-dose glass ampule.

Injection: 5 mL of ethyl alcohol ≥ 99% by volume as a clear, colorless liquid in a single-dose glass vial.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Heart Block

Transient Heart Block
Transient heart block is common at the time of dehydrated alcohol, such as ABLYSINOL, injection into a septal artery. Prior to the injection, a temporary pacing wire is routinely inserted into the apex of the right ventricle, usually via the femoral vein, to treat transient heart block. The pacing lead can be removed if no episode of high-degree atrioventricular block occurs, usually after several hours of observation following percutaneous transluminal septal myocardial ablation.

Persistent Heart Block
Approximately 10% of complete heart block events become permanent and require placement of a permanent pacemaker following percutaneous transluminal septal myocardial ablation. Risk factors for permanent pacemaker dependency after septal ablation include a baseline PQ interval > 160 ms, baseline minimum heart rate < 50 bpm, baseline left ventricular outflow gradient > 70 mmHg, maximum QRS during the first 48 hours > 155 ms, 3rd degree atrio-ventricular block occurring during the procedure, and no clinical recovery between 12-48 hours after the procedure.

5.2 Myocardial Infarction

Injection of dehydrated alcohol is intended to create a controlled myocardial infarction for therapeutic purposes. However, excessive myocardial necrosis and subsequent heart failure have been reported. Factors increasing the risk of excessive tissue necrosis include higher volume of alcohol used and a higher number of septal branches injected to reduce the left ventricular outflow tract gradient.

5.3 Ventricular Arrhythmia

Ventricular tachycardia and ventricular fibrillation requiring electrocardioversion occurred at a frequency of approximately 1%. Perform continuous electrocardiographic monitoring for 48 hours after the procedure.

6 ADVERSE REACTIONS

Heart block [*see Warnings and precautions* (5.1)]

The following other adverse reactions associated with percutaneous transluminal septal myocardial ablation with the use of dehydrated alcohol, such as ABLYSINOL, were identified in the literature: Ventricular tachycardia and ventricular fibrillation.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary
The concentrations of alcohol in blood after PTSMA were not measured, but ABLYSINOL is not expected to increase significantly the systemic concentrations of endogenous alcohol following administration into a septal artery during percutaneous transluminal septal myocardial ablation. Maternal use is not expected to result in fetal exposure to the drug.

Clinical Considerations
ABLYSINOL for percutaneous transluminal septal myocardial ablation has not been evaluated in pregnant women and is not recommended during pregnancy. When possible, the percutaneous transluminal septal myocardial ablation procedure should be postponed in women until the postpartum period.

Data
Animal reproduction studies have shown an adverse effect on the fetus and chronic fetal alcohol exposure is known to cause developmental defects in human. The developmental effects of acute ethanol exposure, such as from percutaneous transluminal septal myocardial ablation, have not been studied in pregnant or lactating women.

8.2 Lactation

ABLYSINOL is not expected to increase significantly the systemic concentrations of endogenous alcohol following administration into a septal artery during percutaneous transluminal septal myocardial ablation and breastfeeding is not expected to result in exposure of the child to the drug.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

A comparison of the outcomes in patients with hypertrophic obstructive cardiomyopathy in patients < 60 years old and in patients ≥ 60 years old showed similar

improvement in exercise capacity after ablation. The rate of heart blocks and dysrhythmia increased with age. Permanent pacemaker dependency increased to 34% in patients > 60 years old.

10 OVERDOSAGE

There is a direct correlation between the volume of alcohol and size of iatrogenic myocardial infarction. Stop the procedure if there is failure to reduce the left ventricular outflow tract pressure gradient to less than 10 mmHg when reaching a total dose of 5 mL.

11 DESCRIPTION

ABLYSINOL (dehydrated alcohol) injection is a sterile, preservative free solution of ≥ 99% by volume ethyl alcohol and no excipients. ABLYSINOL is for cardiac septal branch intra-arterial use. It has a molecular formula of C_2H_6O and a molecular weight of 46.07.

Dehydrated Alcohol Injection, USP is a potent tissue toxin. Ethanol is a clear, colorless, volatile, and flammable liquid miscible with water. It has the following structural formula:

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Dehydrated alcohol is a tissue toxin that produces a myocardial infarction when injected through an intra-arterial catheter into a target septal vessel, which causes the hypertrophied septum to thin.

12.2 Pharmacodynamics

A dose independent, approximate 70% reduction of the peak pressure gradient across left ventricular outflow tract is observed after injection of alcohol volumes in the range of 1-4 mL. Remodeling contributes about 20% to the 70% total reduction in peak pressure gradient across the left ventricular outflow tract measured 12 months after septal ablation. Other markers, such as infarct size or peak concentration of creatine kinase-MB (CK-MB), in contrast to peak pressure gradient across the left ventricular outflow tract, vary in proportion to the injected alcohol volume in the 1-4 mL range.

12.3 Pharmacokinetics

Because injection of ABLYSINOL during septal ablation is not expected to increase the systemic concentrations of endogenous alcohol significantly, the pharmacokinetics of dehydrated alcohol are not expected to be clinically significant.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Ethanol (of alcohol beverages) was added to Group 1 International Agency for Research on Cancer (IARC) Carcinogenicity Ratings (IARC monographs). Substances in this group are either carcinogenic to humans, or there is sufficient evidence of carcinogenicity in experimental animals and strong evidence in exposed humans that the substance acts through a relevant mechanism of carcinogenicity. Alcohol consumption has been associated with various cancers, including liver, esophageal, breast, prostate, and colorectal cancer. Since ABLYSINOL is not expected to reach the systemic circulation following administration into a septal artery during percutaneous transluminal septal myocardial ablation, the recommended clinical use of the drug product is not expected to have carcinogenic risk in patients.

Literature reports suggest that ethanol is not mutagenic in the in vitro bacterial reverse mutation (Ames) assay or in vitro chromosomal aberration assays. Ethanol is metabolized to acetaldehyde, which is a known mutagen.

There are no data from either animal or human studies regarding potential for the impairment of fertility.

13.2 Animal Toxicology and/or Pharmacology

The median lethal dose (LD_{50}) values for ethyl alcohol given by intravenous and oral routes are 1440 and 7060 mg/kg in rats and 1973 and 3450 mg/kg in mice, respectively. The LD_{50} for ethyl alcohol given by subcutaneous injection is 8285 mg/kg in mice.

14 CLINICAL STUDIES

Evidence of the effectiveness of ethanol on exercise capacity in adults with symptomatic hypertrophic obstructive cardiomyopathy who are not candidates for surgical myectomy was obtained from literature involving over 4000 patients.

16 HOW SUPPLIED/STORAGE AND HANDLING

ABLYSINOL (dehydrated alcohol) injection is a clear, colorless liquid supplied in clear, glass, single-dose ampules and single-dose vials. Each mL contains 99% by volume ethyl alcohol.

Volume	**NDC**	
	Single ampule	**Carton of 10 ampules**
1 mL	54288-105-01	54288-105-10
5 mL	54288-105-02	54288-105-15
	Single Vial	**Carton of 10 Vials**
5 mL	54288-144-01	54288-144-10

Store at room temperature, between 20°C and 25°C (68°F and 77°F). Do not refrigerate or freeze. Highly flammable, store away from any heat source.

Ampules:

Manufactured for:

BPI Labs, LLC, Largo, FL 33773 USA

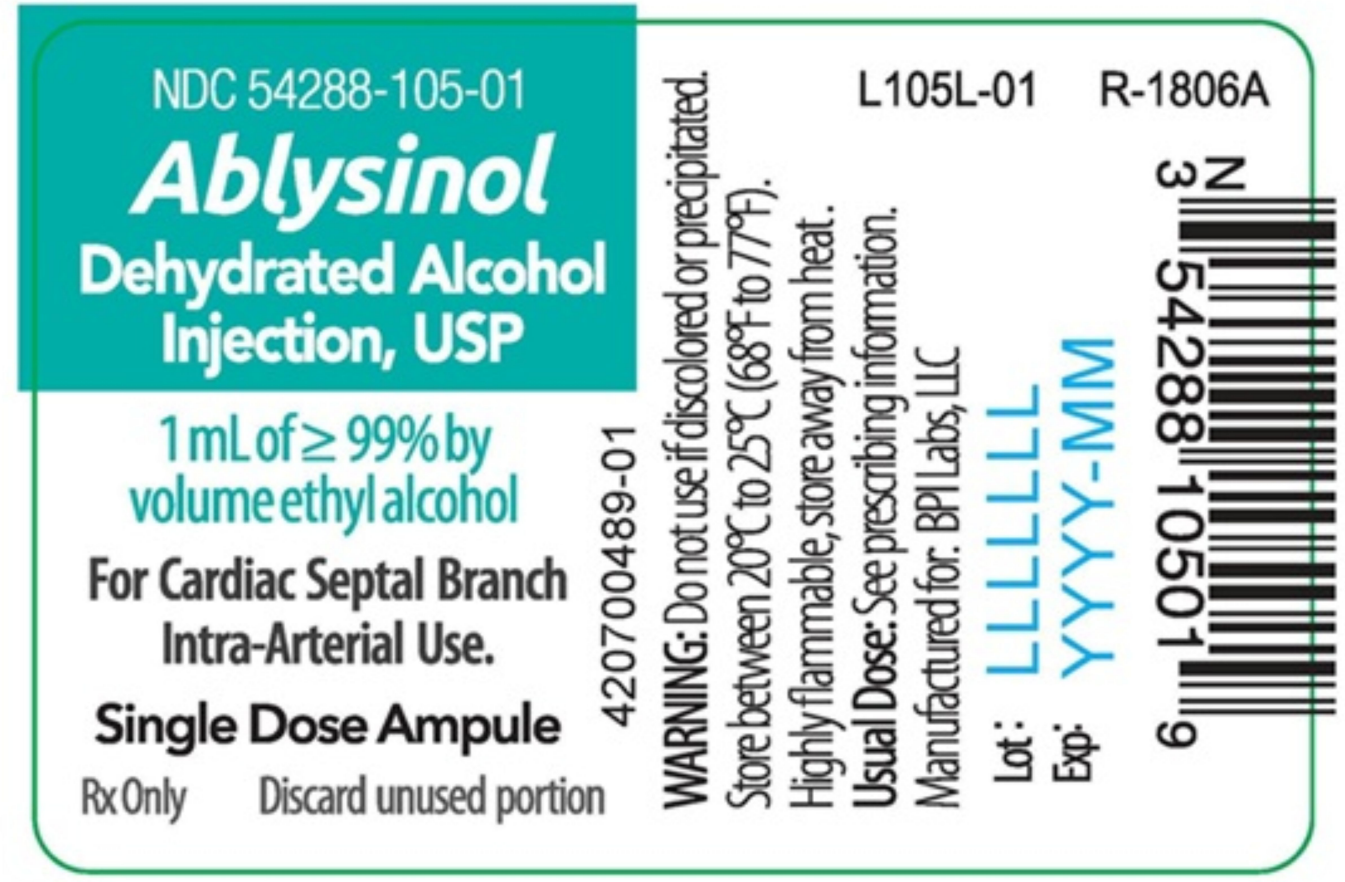
Manufactured by:
Sintetica SA
Via Penate 5
6850 Mendrisio, Switzerland

Vials:

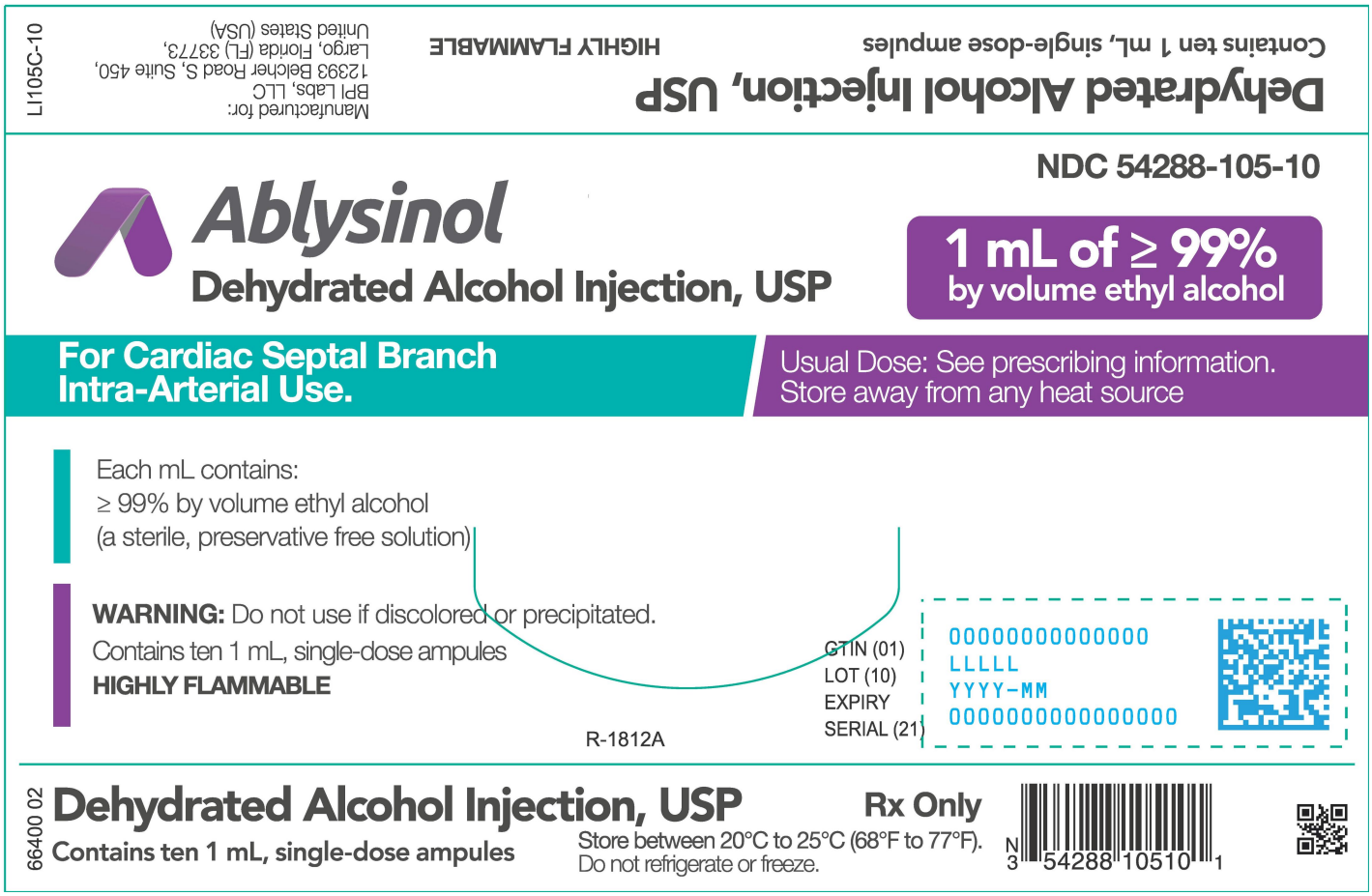
Manufactured by:
BPI Labs, LLC
12393 Belcher Rd S, Suite 450
Largo, FL 33773

PRINCIPAL DISPLAY PANEL - 1 mL AMPULE

ABLYSINOL® (Dehydrated Alcohol Injection, USP)
NDC 54288-105-01
1 mL - AMPULE - LABEL



ABLYSINOL® (Dehydrated Alcohol Injection, USP)
NDC 54288-105-10
1 mL - AMPULE - CARTON - 10 PACK



PRINCIPAL DISPLAY PANEL - 5 mL AMPULE

ABLYSINOL® (Dehydrated Alcohol Injection, USP)

NDC 54288-105-02

5mL - AMPULE - LABEL

NDC 54288-105-02

Ablysinol

Dehydrated Alcohol Injection, USP

5 mL of ≥99% by volume ethyl alcohol

For Cardiac Septal Branch Intra-Arterial Use.

Single Dose Ampule
Discard unused portion

LOT

EXP

Rx Only

WARNING: Do not use if discolored or precipitated.

Store between 20°C to 25°C (68°F to 77°F).

Highly flammable, store away from heat.

Usual Dose: See prescribing information.

Manufactured for:
BPI Labs, LLC

L105L-02 R-1806

N 3 54288 10502 6

68401 01

ABLYSINOL® (Dehydrated Alcohol Injection, USP)
NDC 54288-105-15
5mL - AMPULE - CARTON - 10 PACK

LI105C-15

Manufactured for:
BPI Labs, LLC
12393 Belcher Road S, Suite 450,
Largo, Florida (FL) 33773,
United States (USA)

HIGHLY FLAMMABLE

Contains ten 5 mL, single-dose ampules
Dehydrated Alcohol Injection, USP

NDC 54288-105-15

Ablysinol
Dehydrated Alcohol Injection, USP

5 mL of ≥ 99%
by volume ethyl alcohol

For Cardiac Septal Branch
Intra-Arterial Use.

Usual Dose: See prescribing information.
Store away from any heat source

Each mL contains:
≥ 99% by volume ethyl alcohol
(a sterile, preservative free solution)

WARNING: Do not use if discolored or precipitated.
Contains ten 5 mL, single-dose ampules
HIGHLY FLAMMABLE

R-1806B

GTIN (01) 00000000000000
LOT (10) LLLLL
EXPIRY YYYY-MM
SERIAL (21) 0000000000000000

66401 03

Dehydrated Alcohol Injection, USP
Contains ten 5 mL, single-dose ampules

Rx Only

Store between 20°C to 25°C (68°F to 77°F).
Do not refrigerate or freeze.

N 3 54288 10515 6

PRINCIPAL DISPLAY PANEL - 5 mL VIAL

ABLYSINOL® (Dehydrated Alcohol Injection, USP)

NDC 54288-144-01
5 mL - VIAL - LABEL

NDC 54288-**144**-01 Rx Only

Ablysinol
Dehydrated Alcohol Injection, USP

5 mL of ≥99% by volume ethyl alcohol

For Cardiac Septal Branch Intra-Arterial Use.

Single-Dose Vial
Discard unused portion

LI144L-01 R-2503

WARNING: Do not use if discolored or precipitated.
Store between 20°C to 25°C (68°F to 77°F).
Highly flammable, store away from heat.
Recommended Dosage: See prescribing information.
Manufactured by:
BPI Labs, LLC
12393 Belcher Rd S, Suite 450
Largo, FL 33773 USA

Batch:

EXP:

N 3 54288 14401 8

ABLYSINOL® (Dehydrated Alcohol Injection, USP)
NDC 54288-144-10
5 mL - VIAL - CARTON - 10 PACK

DEHYDRATED ALCOHOL

alcohol injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:54288-105
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	1 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54288-105-10	10 in 1 CARTON	10/24/2018	
1	NDC:54288-105-01	1 mL in 1 AMPULE; Type 0: Not a Combination Product		
2	NDC:54288-105-15	10 in 1 CARTON	10/24/2018	
2	NDC:54288-105-02	5 mL in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information

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

NDA	NDA207987	10/24/2018	

DEHYDRATED ALCOHOL

alcohol injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:54288-144
Route of Administration	PERCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	1 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54288-144-10	10 in 1 CARTON	04/01/2025	
1	NDC:54288-144-01	5 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA207987	04/01/2025	

Labeler - BPI Labs, LLC (078627620)

Establishment

Name	Address	ID/FEI	Business Operations
Sintetica SA		480895478	manufacture(54288-105) , analysis(54288-105) , label(54288-105) , pack(54288-105)

Establishment

Name	Address	ID/FEI	Business Operations
BPI Labs LLC		078627620	manufacture(54288-144) , analysis(54288-144) , label(54288-144)