

GLYCOPYRROLATE - glycopyrrolate injection
Zydus Lifesciences Limited

Glycopyrrolate Injection, USP

Rx only
NOT FOR USE IN NEONATES
CONTAINS BENZYL ALCOHOL

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1616-1

Glycopyrrolate Injection, USP

0.2 mg/mL

NOT FOR USE IN NEWBORNS

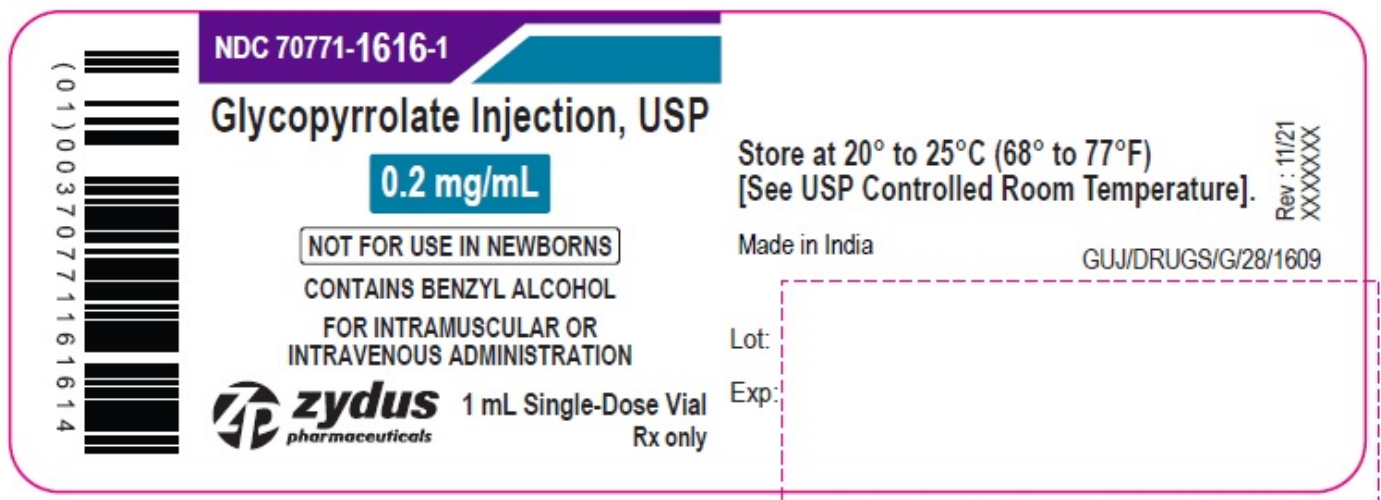
CONTAINS BENZYL ALCOHOL

FOR INTRAMUSCULAR OR

INTRAVENOUS ADMINISTRATION

1 mL Single-Dose Vial

Rx only



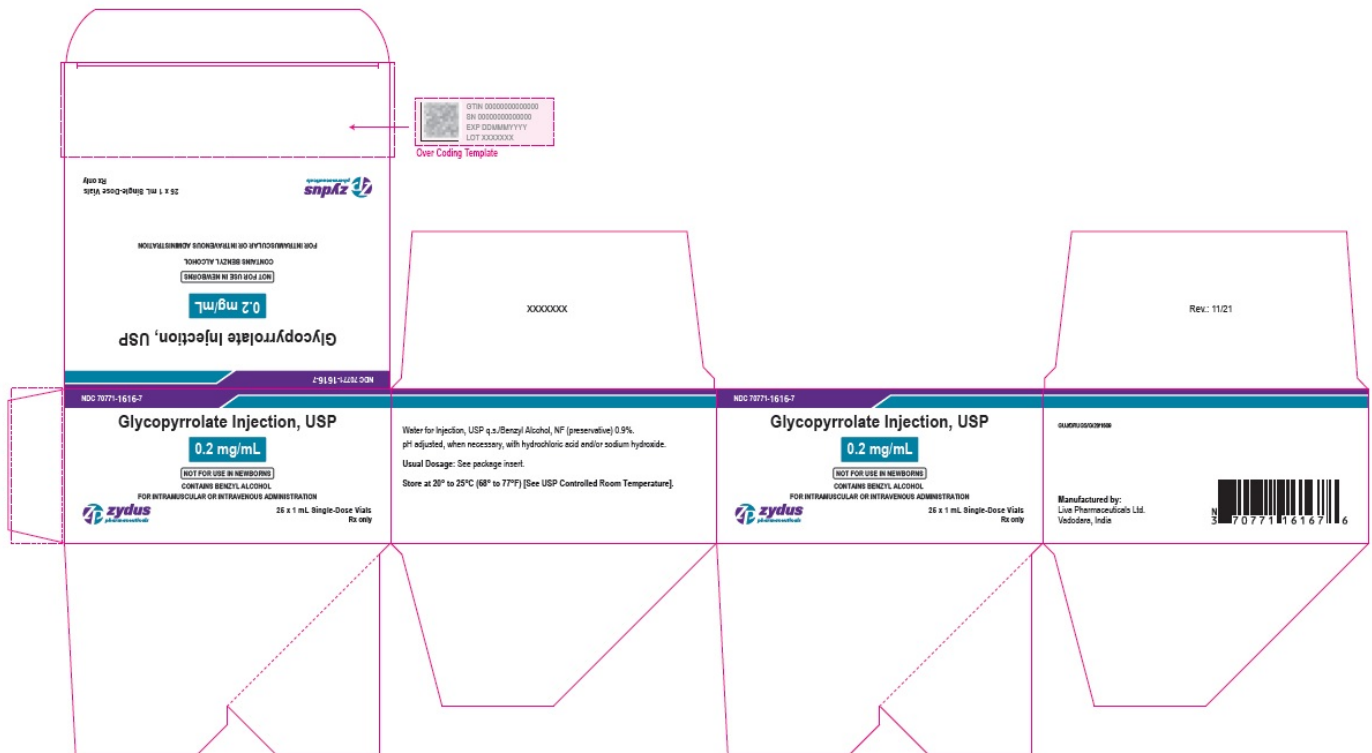
NDC 70771-1616-7

Glycopyrrolate Injection, USP

0.2 mg/mL

NOT FOR USE IN NEWBORNS

CONTAINS BENZYL ALCOHOL
FOR INTRAMUSCULAR OR INTRAVENOUS ADMINISTRATION
25 x 1 mL Single-Dose Vials
Rx only



NDC 70771-1617-1
Glycopyrrolate Injection, USP
0.4 mg/2 mL
(0.2 mg/mL)
NOT FOR USE IN NEWBORNS
CONTAINS BENZYL ALCOHOL
FOR INTRAMUSCULAR OR
INTRAVENOUS ADMINISTRATION
2 mL Single-Dose Vial
Rx only

(01)00370771161713

NDC 70771-1617-1

Glycopyrrolate Injection, USP

0.4 mg/2 mL
(0.2 mg/mL)

NOT FOR USE IN NEWBORNS
CONTAINS BENZYL ALCOHOL
FOR INTRAMUSCULAR OR
INTRAVENOUS ADMINISTRATION

zydus pharmaceuticals 2 mL Single-Dose Vial
Rx only

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].

Made in India

GUJ/DRUGS/G/28/1609

Rev : 11/21
XXXXXX

Lot: _____

Exp: _____

NDC 70771-1617-7

Glycopyrrolate Injection, USP

0.4 mg/2 mL

(0.2 mg/mL)

NOT FOR USE IN NEWBORNS

CONTAINS BENZYL ALCOHOL

FOR INTRAMUSCULAR OR INTRAVENOUS ADMINISTRATION

25 x 2 mL Single-Dose Vials

Rx only

Over Coding Template

GTIN 03000000000000
SN 00000000000000
EXP 00000000000000
LOT XXXXXXXX

25 x 2 mL Single-Dose Vials
Rx only

zydus pharmaceuticals

Glycopyrrolate Injection, USP

0.4 mg/2 mL
(0.2 mg/mL)

NOT FOR USE IN NEWBORNS
CONTAINS BENZYL ALCOHOL

FOR INTRAMUSCULAR OR INTRAVENOUS ADMINISTRATION

Water for Injection, USP (s.s. Benzyl Alcohol, NF (preservative) 0.5%
pH adjusted, when necessary, with hydrochloric acid and/or sodium hydroxide.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

zydus pharmaceuticals

Glycopyrrolate Injection, USP

0.4 mg/2 mL
(0.2 mg/mL)

NOT FOR USE IN NEWBORNS
CONTAINS BENZYL ALCOHOL

FOR INTRAMUSCULAR OR INTRAVENOUS ADMINISTRATION

25 x 2 mL Single-Dose Vials
Rx only

zydus pharmaceuticals

Manufactured by:
LIFE PHARMACEUTICALS LTD.
Vadodra, India

Rev: 11/21

70771161713

NDC 70771-1618-1

Glycopyrrolate Injection, USP

1 mg/5 mL

(0.2 mg/mL)

NOT FOR USE IN NEWBORNS

CONTAINS BENZYL ALCOHOL

FOR INTRAMUSCULAR OR

INTRAVENOUS ADMINISTRATION

5 mL Multiple-Dose Vial

Rx only

(01)00370771161812

NDC 70771-1618-1

**Glycopyrrolate
Injection, USP**

**1 mg/5 mL
(0.2 mg/mL)**

NOT FOR USE IN NEWBORNS
CONTAINS BENZYL ALCOHOL
FOR INTRAMUSCULAR OR
INTRAVENOUS ADMINISTRATION

zydus
pharmaceuticals

5 mL Multiple-Dose Vial
Rx only

Water for Injection, USP q.s./Benzyl Alcohol,
NF (preservative) 0.9%.
pH adjusted, when necessary,
with hydrochloric acid and/or sodium hydroxide.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].
Made in India

Lot: _____
Exp: _____

GLJDRUGS/G28/1609
Rev: 11/21
XXXXXX

NDC 70771-1618-7

Glycopyrrolate Injection, USP

1 mg/5 mL

(0.2 mg/mL)

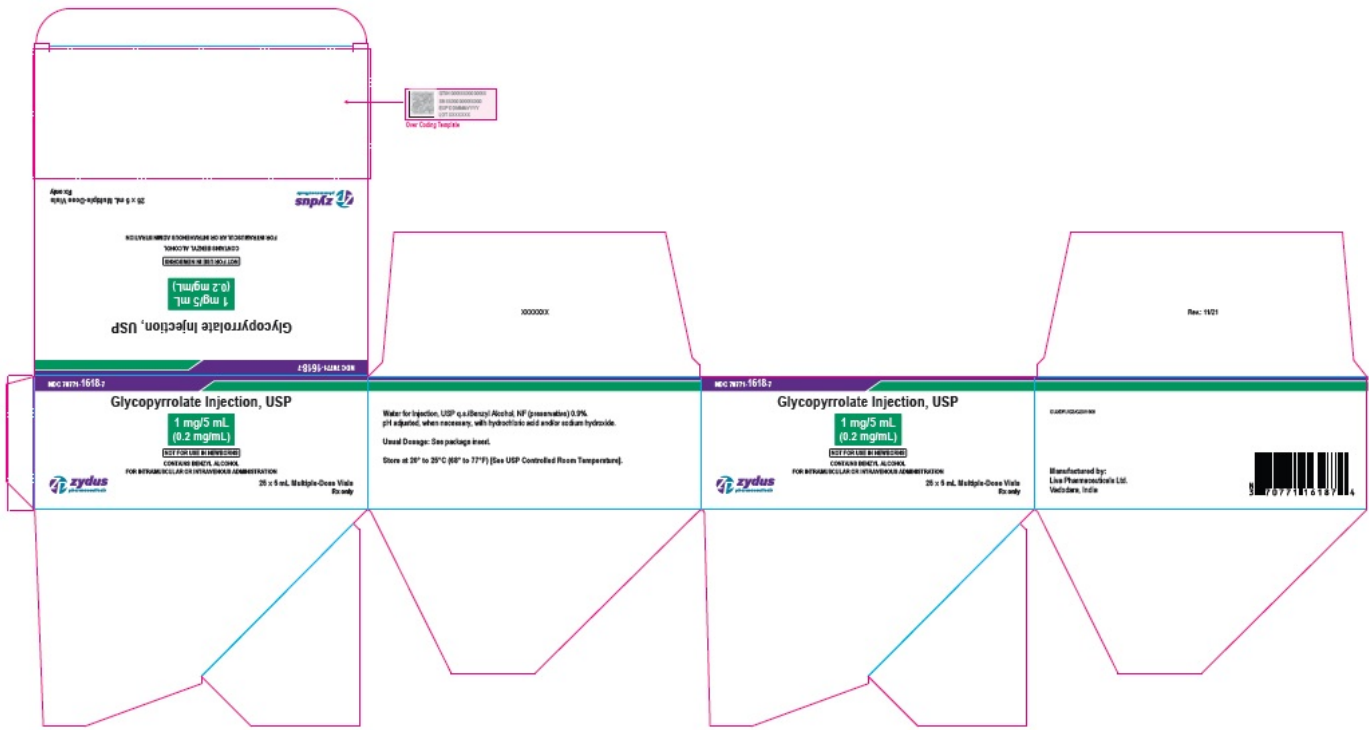
NOT FOR USE IN NEWBORNS

CONTAINS BENZYL ALCOHOL

FOR INTRAMUSCULAR OR INTRAVENOUS ADMINISTRATION

25 x 5 mL Multiple-Dose Vials

Rx only



NDC 70771-1619-1

Glycopyrrolate Injection, USP

4 mg/20 mL

(0.2 mg/mL)

NOT FOR USE IN NEWBORNS


CONTAINS BENZYL ALCOHOL

FOR INTRAMUSCULAR OR

INTRAVENOUS ADMINISTRATION

20 mL Multiple-Dose Vial

Rx only



(01)00370771161812

NDC 70771-1619-1

Glycopyrrolate Injection, USP

**4 mg/20 mL
(0.2 mg/mL)**

NOT FOR USE IN NEWBORNS
CONTAINS BENZYL ALCOHOL
FOR INTRAMUSCULAR OR
INTRAVENOUS ADMINISTRATION

zydus pharmaceuticals

20 mL Multiple-Dose Vial
Rx only

Water for Injection, USP q.s./Benzyl Alcohol, NF (preservative) 0.9%.
pH adjusted, when necessary, with hydrochloric acid and/or sodium hydroxide.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].
Made in India

Rev: 11/21
XXXXXX

GUJ/DRUGS/G/28/1609

Lot: _____

Exp: _____

NDC 70771-1619-6

Glycopyrrolate Injection, USP

4 mg/20 mL

(0.2 mg/mL)

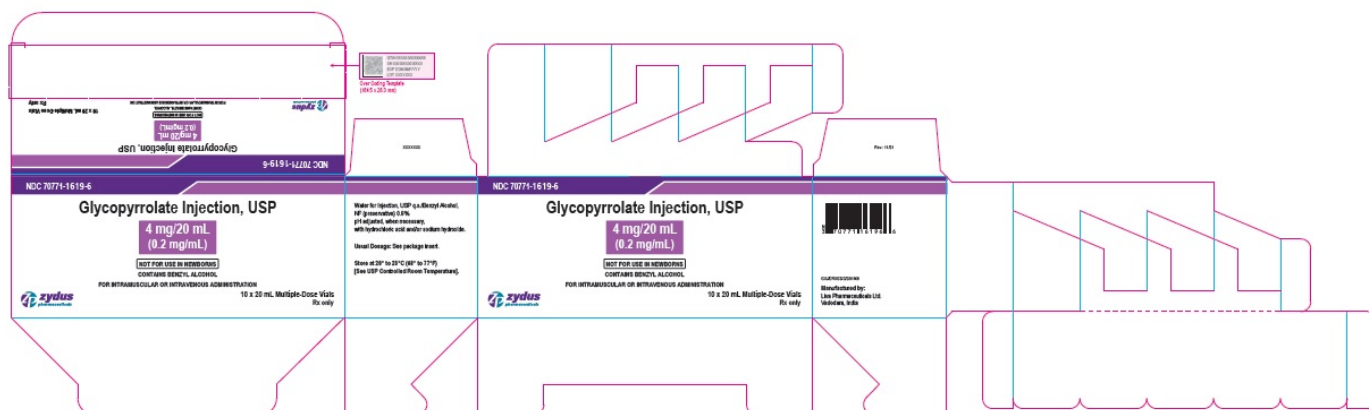
NOT FOR USE IN NEWBORNS

CONTAINS BENZYL ALCOHOL

FOR INTRAMUSCULAR OR INTRAVENOUS ADMINISTRATION

10 x 20 mL Multiple-Dose Vials

Rx only



GLYCOPYRROLATE

glycopyrrolate injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1616
Route of Administration	INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCOPYRROLATE (UNII: V92SO9WP2I) (GLYCOPYRRONIUM - UNII:A14FB57V1D)	GLYCOPYRROLATE	0.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	9 mg in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	

SODIUM HYDROXIDE (UNII: 55X04QC32I)

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1616-6	25 in 1 CARTON	11/18/2021	
1	NDC:70771-1616-1	1 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214213	11/18/2021	

GLYCOPYRROLATE

glycopyrrolate injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1617
Route of Administration	INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCOPYRROLATE (UNII: V92S09WP2I) (GLYCOPYRRONIUM - UNII:A14FB57V1D)	GLYCOPYRROLATE	0.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	9 mg in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1617-7	2 mL in 1 VIAL; Type 0: Not a Combination Product	11/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214213	11/18/2021	

GLYCOPYRROLATE

glycopyrrolate injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1618
Route of Administration	INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCOPYRROLATE (UNII: V92S09WP2I) (GLYCOPYRRONIUM - UNII:A14FB57V1D)	GLYCOPYRROLATE	0.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	9 mg in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1618-7	25 in 1 CARTON	11/18/2021	
1	NDC:70771-1618-1	5 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214213	11/18/2021	

GLYCOPYRROLATE

glycopyrrolate injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1619
Route of Administration	INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCOPYRROLATE (UNII: V92SO9WP2I) (GLYCOPYRRONIUM - UNII:A14FB57V1D)	GLYCOPYRROLATE	0.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	9 mg in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1619-6	10 in 1 CARTON	11/18/2021	
1	NDC:70771-1619-1	20 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214213	11/18/2021	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		873671928	MANUFACTURE(70771-1616, 70771-1617, 70771-1618, 70771-1619) , ANALYSIS(70771-1616, 70771-1617, 70771-1618, 70771-1619)