

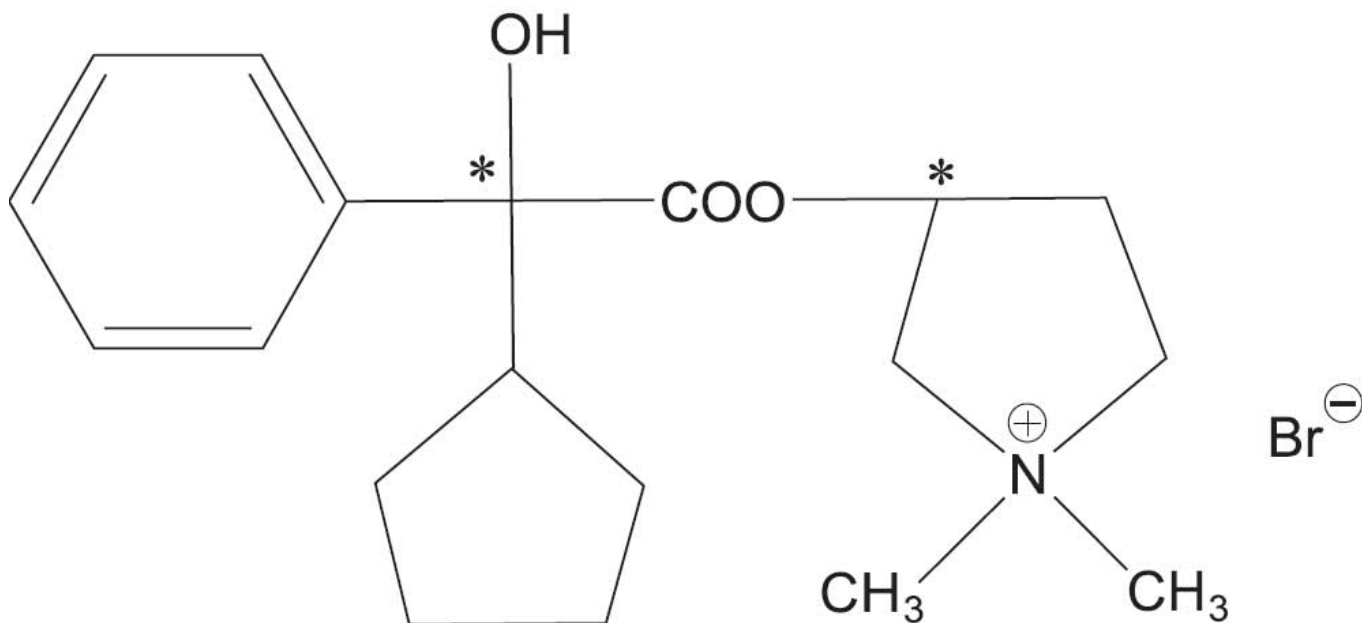
GLYCOPYRROLATE - glycopyrrolate tablet
Par Formulations Private Limited

Glycopyrrolate Tablets USP

DESCRIPTION

Glycopyrrolate tablets contain the synthetic anticholinergic glycopyrrolate. Glycopyrrolate is a quaternary ammonium compound with the following chemical name: 3-[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-

dimethylpyrrolidinium bromide. Its empirical formula is $C_{19}H_{28}BrNO_3$, its molecular weight is 398.33, and its structural formula is:



Each 1 mg tablet contains: Glycopyrrolate, USP1 mg

Each 2 mg tablet contains: Glycopyrrolate, USP2 mg

Inactive Ingredients: Dibasic Calcium Phosphate, Lactose, Magnesium Stearate, Povidone, Sodium Starch Glycolate.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Rising[®] NDC 64980-272-01

Glycopyrrolate Tablets, USP

1 mg

100 Tablets

Rx only

Each tablet contains:
Glycopyrrolate, USP 1 mg
USUAL DOSAGE: One or two tablets three times a day. See accompanying information.

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.

Pharmacist: Dispense in tight container.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Manufactured for:
Rising Pharmaceuticals, Inc.
Allendale, NJ 07401

Product of Finland
Manufactured by:
Par Formulations Private Limited,
1/58, Pudupakkam,
Kelambakkam - 603 103.
Made in India
from Active Pharmaceutical
Ingredient made in Finland
Mfg. Lic. No.: TN00002121



LA272R-01-74-01
Iss. 02-2016

Control No.:

Exp. Date:

Rising[®] NDC 64980-273-01

Glycopyrrolate Tablets, USP

2 mg

100 Tablets

Rx only

Each tablet contains:
Glycopyrrolate, USP 2 mg
USUAL DOSAGE: One tablet two or three times a day. See accompanying information.

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.

Pharmacist: Dispense in tight container.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Manufactured for:
Rising Pharmaceuticals, Inc.
Allendale, NJ 07401

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1/58, Pudupakkam,
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Made in India
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GLYCOPYRROLATE

glycopyrrolate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:43227-065
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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GLYCOPYRROLATE (UNII: V92SO9WP2I) (GLYCOPYRRONIUM - UNII:A14FB57V1D)		GLYCOPYRROLATE	1 mg	
Inactive Ingredients				
Ingredient Name		Strength		
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)				
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
POVIDONES (UNII: FZ989GH94E)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
Product Characteristics				
Color	WHITE	Score	2 pieces	
Shape	ROUND	Size	8mm	
Flavor		Imprint Code	K;400	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43227-065-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/26/2006	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA040653	09/26/2006		

GLYCOPYRROLATE			
glycopyrrolate tablet			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:43227-066
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
GLYCOPYRROLATE (UNII: V92SO9WP2I) (GLYCOPYRRONIUM - UNII:A14FB57V1D)		GLYCOPYRROLATE	2 mg
Inactive Ingredients			
Ingredient Name		Strength	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)			
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)			

MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONES (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE	Score	2 pieces
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	K;401
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43227-066-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/26/2006	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040653	09/26/2006	

Labeler - Par Formulations Private Limited (676159161)

Registrant - Par Formulations Private Limited (676159161)