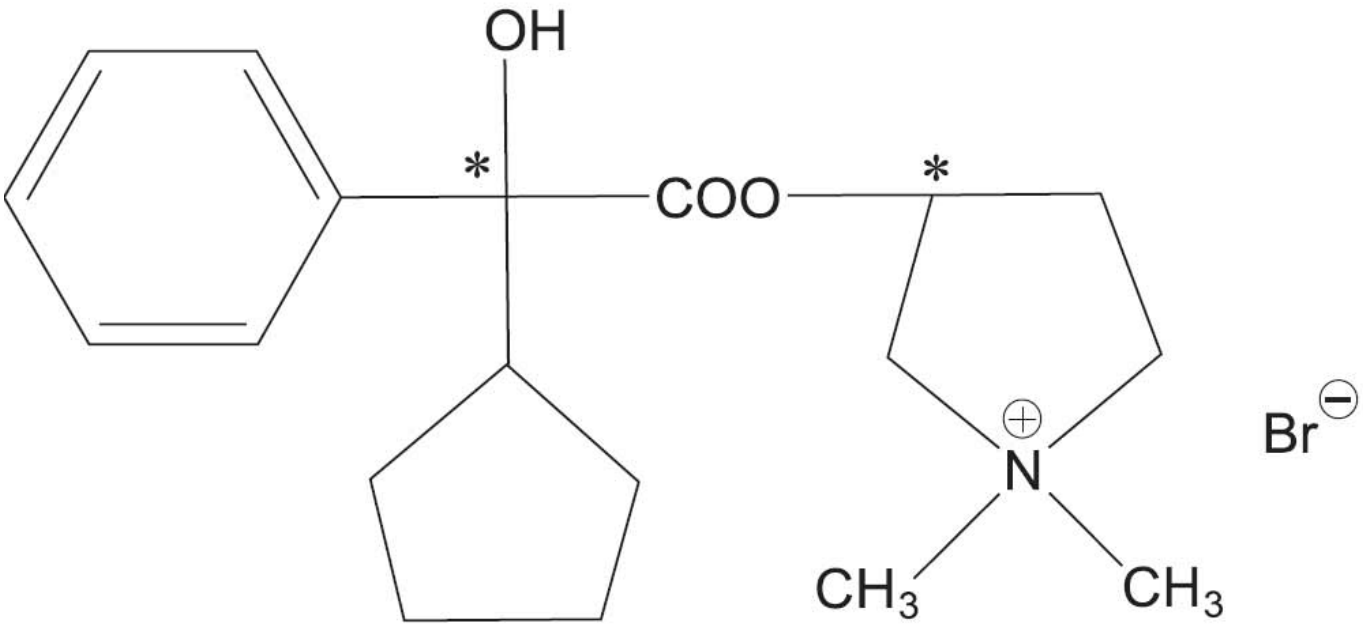
GLYCOPYRROLATE - glycopyrrolate tablet
Par Formulations Private Limited

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:

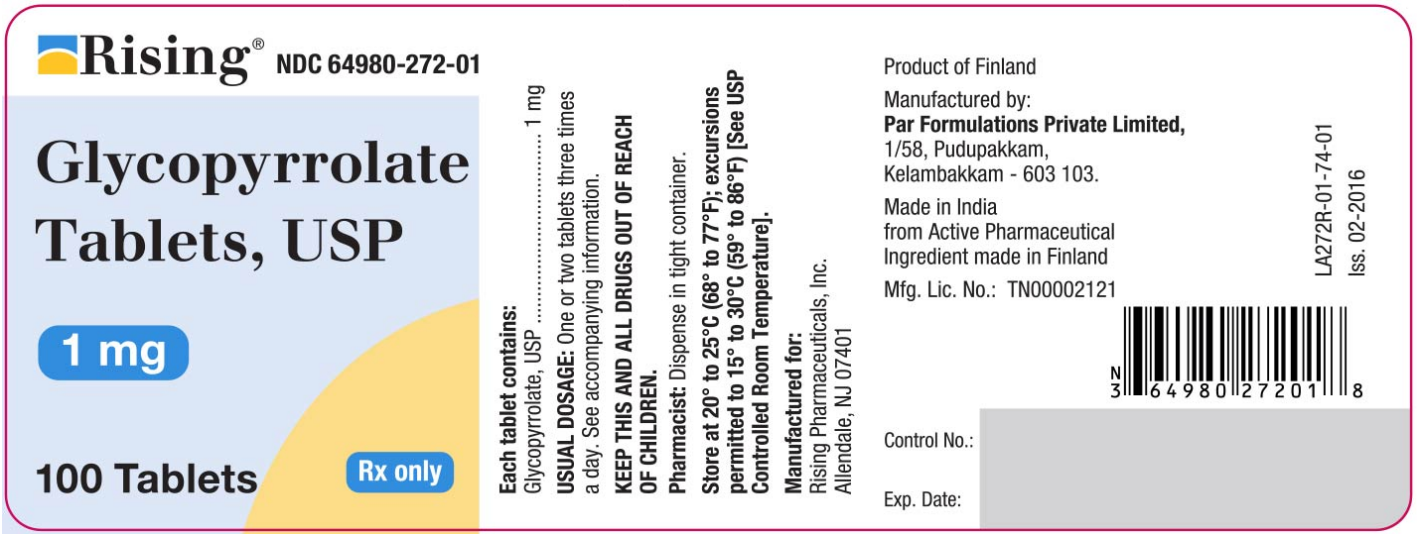


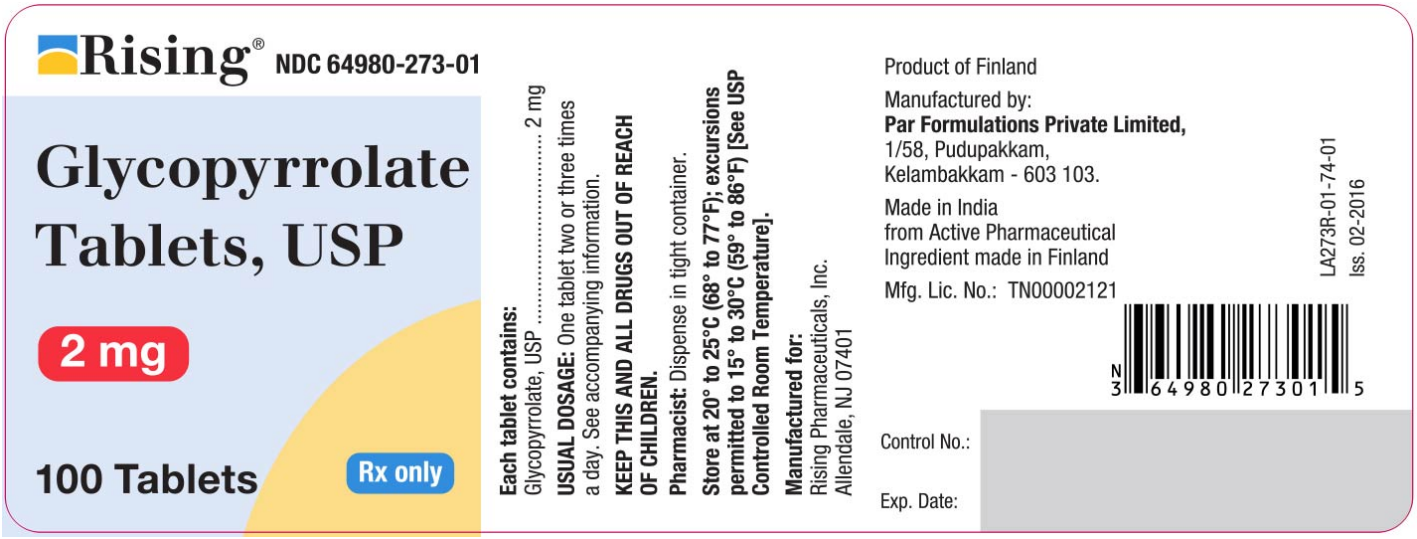
Each 1 mg tablet contains: Glycopyrrolate, USP .....1 mg

Each 2 mg tablet contains: Glycopyrrolate, USP .....2 mg

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

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





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**

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**	10mm
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)

Revised: 7/2016 Par Formulations Private Limited