GLYCOPYRROLATE - glycopyrrolate tablet
Rising Pharma Holdings, Inc.

Glycopyrrolate Tablets,USP

DESCRIPTION

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

Glycopyrrolate Tablets USP, 1 mg are white, round, flat-faced, beveled edge tablet, debossed "CS" and "007" on one side and scored on the other side.
Each tablet contains: Glycopyrrolate, USP ..... 1 mg

Glycopyrrolate Tablets USP, 2 mg are white, round, flat-faced, beveled edge tablet, debossed "CS" score "008" on one side and plain on the other side.
Each tablet contains: Glycopyrrolate, USP..... 2 mg

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

ACTIONS

Glycopyrrolate, like other anticholinergic (antimuscarinic) agents, inhibits the action of acetylcholine on structures innervated by postganglionic cholinergic nerves and on smooth muscles that respond to acetylcholine but lack cholinergic innervation. These peripheral cholinergic receptors are present in the autonomic effector cells of smooth muscle, cardiac muscle, the sino-atrial node, the atrioventricular node, exocrine glands, and, to a limited degree, in the autonomic ganglia. Thus, it diminishes the volume and free acidity of gastric secretions and controls excessive pharyngeal, tracheal, and bronchial secretions.

Glycopyrrolate antagonizes muscarinic symptoms (e.g., bronchorrhea, bronchospasm, bradycardia, and intestinal hypermotility) induced by cholinergic drugs such as the anticholinesterases.

The highly polar quaternary ammonium group of glycopyrrolate limits its passage across lipid membranes, such as the blood-brain barrier, in contrast to atropine sulfate and scopolamine hydrobromide, which are non-polar tertiary amines which penetrate lipid barriers easily.

INDICATIONS

For use as adjunctive therapy in the treatment of peptic ulcer.

CONTRAINDICATIONS

Glaucoma; obstructive uropathy (for example, bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the gastrointestinal tract (as in achalasia, pyloroduodenal stenosis, etc.); paralytic ileus; intestinal atony of the elderly or debilitated patient; unstable cardiovascular status in acute hemorrhage; severe ulcerative colitis; toxic megacolon complicating ulcerative colitis; myasthenia gravis. Glycopyrrolate tablets are contraindicated in those patients with a hypersensitivity to glycopyrrolate.

WARNINGS

In the presence of a high environmental temperature, heat prostration (fever and heat stroke due to decreased sweating) can occur with use of glycopyrrolate.

Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance treatment with this drug would be inappropriate and possibly harmful.

Glycopyrrolate may produce drowsiness or blurred vision. In this event, the patient should be warned not to engage in activities requiring mental alertness such as operating a motor vehicle or other machinery, or performing hazardous work while taking this drug.
Theoretically, with overdosage, a curare-like action may occur, i.e., neuro-muscular blockade leading to muscular weakness and possible paralysis.

Pregnancy
The safety of this drug during pregnancy has not been established. The use of any drug during pregnancy requires that the potential benefits of the drug be weighed against possible hazards to mother and child. Reproduction studies in rats revealed no teratogenic effects from glycopyrrolate; however, the potent anticholinergic action of this agent resulted in diminished rates of conception and of survival at weaning, in a dose-related manner. Other studies in dogs suggest that this may be due to diminished seminal secretion which is evident at high doses of glycopyrrolate. Information on possible adverse effects in the pregnant female is limited to uncontrolled data derived from marketing experience. Such experience has revealed no reports of teratogenic or other fetus-damaging potential. No controlled studies to establish the safety of the drug in pregnancy have been performed.

Nursing Mothers
It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

Pediatric Use
Since there is no adequate experience in pediatric patients who have received this drug, safety and efficacy in pediatric patients have not been established.

PRECAUTIONS

Use Glycopyrrolate tablets with caution in the elderly and in all patients with:
• Autonomic neuropathy.

• Hepatic or renal disease.
• Ulcerative colitis–large doses may suppress intestinal motility to the point of producing a paralytic ileus and for this reason may precipitate or aggravate "toxic megacolon," a serious complication of the disease.
• Hyperthyroidism, coronary heart disease, congestive heart failure, cardiac tachyarrhythmias, tachycardia, hypertension and prostatic hypertrophy.
• Hiatal hernia associated with reflux esophagitis, since anticholinergic drugs may aggravate this condition.

ADVERSE REACTIONS

Anticholinergics produce certain effects, most of which are extensions of their fundamental pharmacological actions. Adverse reactions to anticholinergics in general may include xerostomia; decreased sweating; urinary hesitancy and retention; blurred vision; tachycardia; palpitations; dilatation of the pupil; cycloplegia; increased ocular tension; loss of taste; headaches; nervousness; mental confusion; drowsiness; weakness; dizziness; insomnia; nausea; vomiting; constipation; bloated feeling; impotence; suppression of lactation; severe allergic reaction or drug idiosyncrasies including anaphylaxis, urticaria and other dermal manifestations.

Glycopyrrolate is chemically a quaternary ammonium compound; hence, its passage across lipid membranes, such as the blood-brain barrier, is limited in contrast to atropine sulfate and scopolamine hydrobromide. For this reason the occurrence of CNS related side effects is lower, in comparison to their incidence following administration of anticholinergics which are chemically tertiary amines that can cross this barrier readily.
To report SUSPECTED ADVERSE REACTIONS, contact Rising Pharma Holdings, Inc. at 1-844-874-7464 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

The symptoms of overdosage of glycopyrrolate are peripheral in nature rather than central.

1. To guard against further absorption of the drug-use gastric lavage, cathartics and/or enemas.
2. To combat peripheral anticholinergic effects (residual mydriasis, dry mouth, etc.)–utilize a quaternary ammonium anticholinesterase, such as neostigmine methylsulfate.
3. To combat hypotension–use pressor amines (norepinephrine, metaraminol) i.v.; and supportive care.
4. To combat respiratory depression–administer oxygen; utilize a respiratory stimulant such as Dopram® i.v.; artificial respiration.

DOSAGE AND ADMINISTRATION

The dosage of Glycopyrrolate Tablets USP, 1 mg or Glycopyrrolate Tablets USP, 2 mg should be adjusted to the needs of the individual patient to assure symptomatic control with a minimum of adverse reactions. The presently recommended maximum daily

dosage of glycopyrrolate is 8 mg.

Glycopyrrolate Tablets USP, 1 mg. The recommended initial dosage of Glycopyrrolate Tablets USP, 1 mg for adults is one tablet three times daily (in the morning, early afternoon, and at bedtime). Some patients may require two tablets at bedtime to assure overnight control of symptoms. For maintenance, a dosage of one tablet twice a day is frequently adequate.

Glycopyrrolate Tablets USP, 2 mg. The recommended dosage of Glycopyrrolate Tablets USP, 2 mg for adults is one tablet two or three times daily at equally spaced intervals.

Glycopyrrolate Tablets are not recommended for use in pediatric patients under the age of 12 years.

DRUG INTERACTIONS
There are no known drug interactions.

HOW SUPPLIED

Glycopyrrolate Tablets USP, 1 mg are supplied as:
Bottles of 30 NDC 16571-743-03
Bottles of 90 NDC 16571-743-09

Glycopyrrolate Tablets USP, 2 mg are supplied as:
Bottles of 30 NDC 16571-744-03
Bottles of 90 NDC 16571-744-09

Store at controlled room temperature, 20°C to 25°C (68°F to 77°F); excursions permitted to 15°- 30°C (59°- 86°F) [see USP Controlled Room Temperature]. Keep out of reach of children.

Dispense in tight container.
℞ only

PIA74409-01

Distributed by:
Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

Manufactured by:
Suven Pharmaceuticals Limited,
Telangana, India

M.L.No.: 24/MD/AP/2009/F/CC
Issued: 06/2021

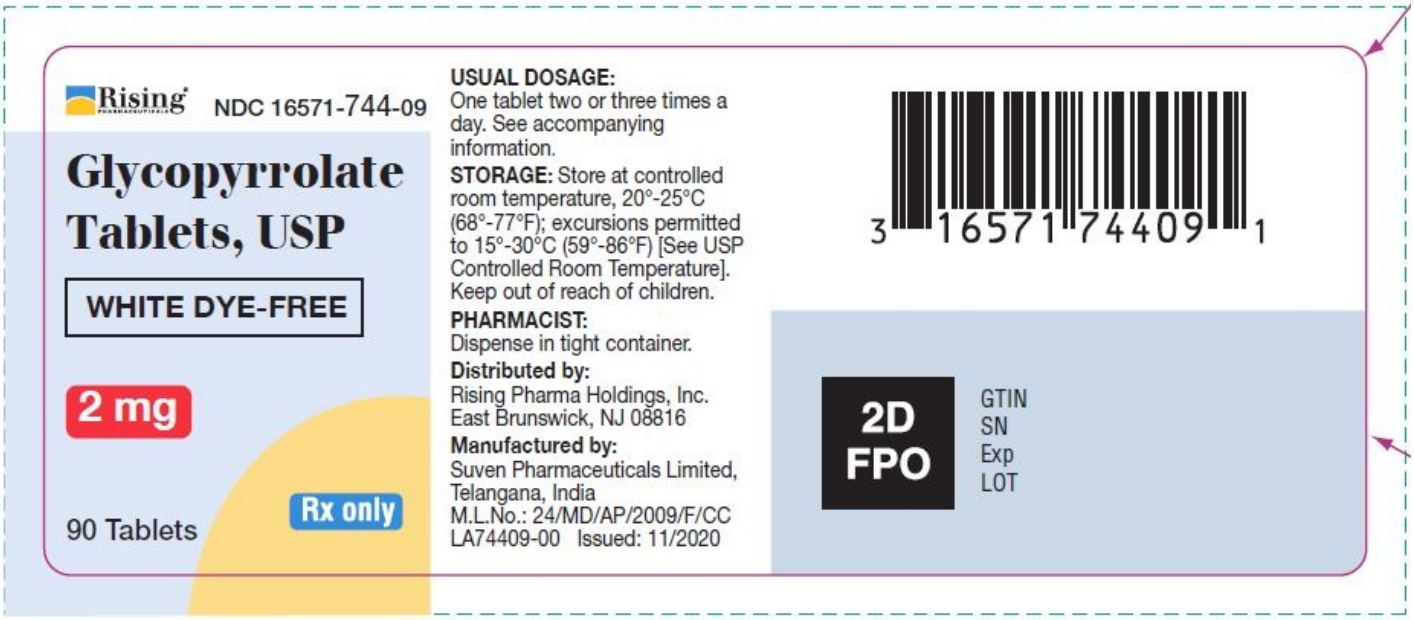
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Rising ® **NDC 16571-743-09**

Glycopyrrolate
Tablets, USP
WHITE DYE-FREE
1 mg
90 Tablets **Rx only**

Rising ® **NDC 16571-744-09**

Glycopyrrolate
Tablets, USP
WHITE DYE-FREE
2 mg
90 Tablets **Rx only**



GLYCOPYRROLATE
glycopyrrolate tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:16571-743
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**
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	WHITE	**Score**	2 pieces
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	CS;007
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:16571-743-03	30 in 1 CONTAINER; Type 0: Not a Combination Product	10/06/2020	
2	NDC:16571-743-09	90 in 1 CONTAINER; Type 0: Not a Combination Product	10/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA AUTHORIZED GENERIC	NDA012827	10/06/2020	

GLYCOPYRROLATE

glycopyrrolate tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:16571-744
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
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE	**Score**	2 pieces
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	CS;008
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16571-744-03	30 in 1 CONTAINER; Type 0: Not a Combination Product	10/06/2020	
2	NDC:16571-744-09	90 in 1 CONTAINER; Type 0: Not a Combination Product	10/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA AUTHORIZED GENERIC	NDA012827	10/06/2020	

Labeler - Rising Pharma Holdings, Inc. (835513529)

Establishment

Name	Address	ID/FEI	Business Operations
Suven Pharmaceuticals Limited		677604288	ANALYSIS(16571-743, 16571-744) , LABEL(16571-743, 16571-744) , MANUFACTURE(16571-743, 16571-744) , PACK(16571-743, 16571-744)

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