GLYCOPYRROLATE- glycopyrrolate tablet
Stason Pharmaceuticals, Inc.

Glycopyrrolate 1 mg 2 mg

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

Inactive Ingredients: Microcrystalline Cellulose. Lactose Monohydrate. Pregelatinized Starch and Magnesium Stearate

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.

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 by 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 arenon-polar tertiaryamines which penetrate lipid barriers easily.

WARNINGS
In the presence of a high environmental temperature. heat prostration (fever and heat stroke due to decreased sweating) can occur with the 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 tomuscular 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 dimished 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 safely 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 drygs 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 has not been established.

PRECAUTIONS
Use Glycopyrrolate 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 the "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; dilation 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 quarternary ammonium compound: hence. its passage across lipid membranes such as the blood-brain barrier. is limited to 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.

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 hydriasis, dry mouth, etc.) - utilize a quartenary ammonium anticholinesterase. such as neostigmine methylsulfate.
3. To combat hypotension- use pressor amines(norepinephrine, metaraminol) i.v.; and supportive car.
4. To combat respiratory depression - administer oxygen: utilize a respuarory stimulant such as Dopram(R) i.v., artificial respiration.

Dosage and Administration

The dosage of glycopyrrolate 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 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.
Glycopyrrolare tablets are not recommended for use in pediatric patients under the age of 12 years.

Drug Interactions

There are no known drug interactions.

Glycopyrrolate Tablets UsP, 1 mg in bottles of 100 (NDC 60763-0475-2)

Store at controlled room temperature, 20C to 25C (68F to 77F); excursions permitted to 15C-30C (59F-86F) [See USP Controlled Room Temperature]. Keep out of reach of children.
Dispense In tight container.
Rx only
Manufactured by:
Stason Pharmaceuticals Inc.
Irvine, CA 92618

Product Label

NDC 60763-475

100 Tablets

Glycopyrrolate Tablets, USP

Rx only

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

Pharmacist: Dispense in tight container.

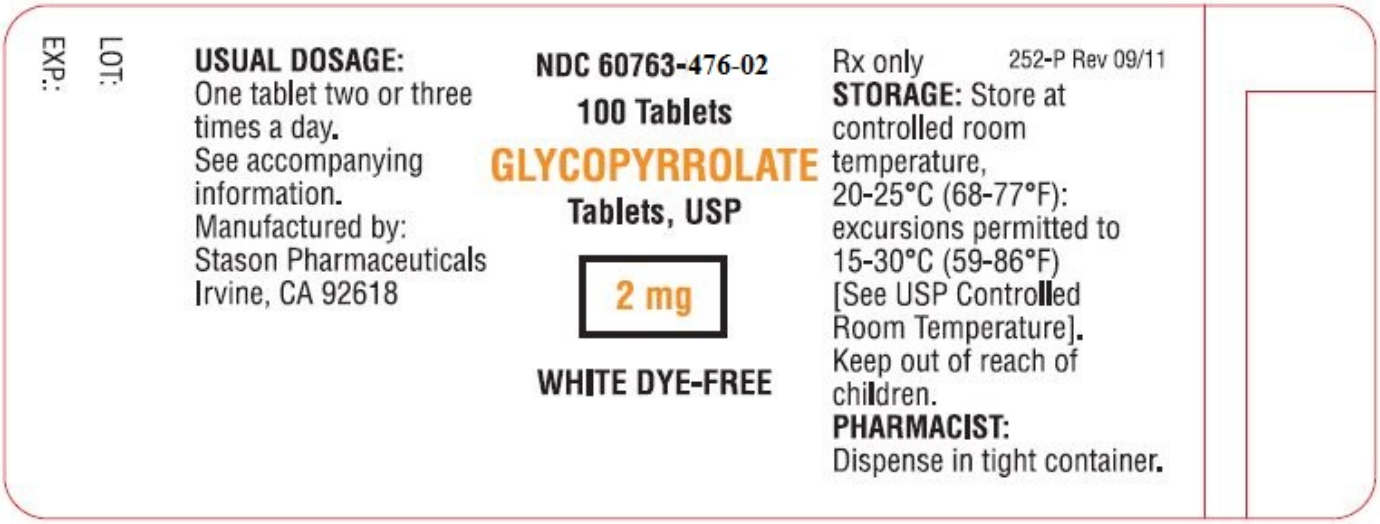
Usual Dosage: One or two tablets three times a day.

See accompanying information.

Manufactured by Stason Pharmaceuticals

Irvine, CA 92618

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 2 mg container text



GLYCOPYRROLATE

glycopyrrolate tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60763-475
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**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, CORN (UNII: O8232NY3SJ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	0475
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:60763-475-02	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091182	04/10/2017	

GLYCOPYRROLATE

glycopyrrolate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60763-476
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
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, CORN (UNII: O8232NY3SJ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	0476
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60763-476-02	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091182	04/10/2017	

Labeler - Stason Pharmaceuticals, Inc. (807437553)

Registrant - Stason Pharmaceuticals, Inc. (807437553)

Establishment

Name	Address	ID/FEI	Business Operations
Stason Pharmaceuticals, Inc.		807437553	manufacture(60763-475, 60763-476)

Revised: 11/2018 Stason Pharmaceuticals, Inc.