

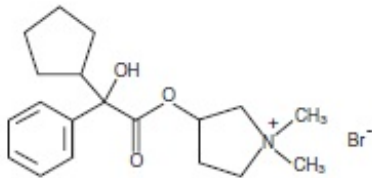
## **GLYCOPYRROLATE- glycopyrrolate tablet Bryant Ranch Prepack**

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### **GLYCOPYRROLATE TABLETS, USP 1 mg and 2 mg Rx only**

#### **DESCRIPTION**

Glycopyrrolate Tablet, USP contain the synthetic anticholinergic, glycopyrrolate. Glycopyrrolate is a quaternary ammonium compound with the following chemical name: 3-[(cyclopentylhydroxyphenyl)acetyl]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, and 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 Tablet, USP 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 Tablet, USP.

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 Tablet, USP may produce drowsiness and 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 Tablet, USP 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.

**CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS. YOU MAY REPORT SIDE EFFECTS TO THE FDA AT 1-800-FDA-1088 OR LEADING PHARMA, LLC AT 1-844-740-7500.**

## **OVERDOSAGE**

The symptoms of overdosage of Glycopyrrolate Tablet, USP 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

methysulfate.

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<sup>®</sup> i.v.; artificial respiration.

## **DOSAGE AND ADMINISTRATION**

The dosage of Glycopyrrolate Tablet, USP 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 Tablet, USP 1 mg. The recommended initial dosage of Glycopyrrolate Tablet, USP 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 Tablet, USP 2 mg. The recommended dosage of Glycopyrrolate Tablet, USP for adults is one tablet two or three times daily at equally spaced intervals.

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

## **DRUG INTERACTIONS**

There are no known drug interactions.

## **HOW SUPPLIED**

NDC: 71335-0020-1: 30 Tablets in a BOTTLE

NDC: 71335-0020-2: 90 Tablets in a BOTTLE

NDC: 71335-0020-3: 28 Tablets in a BOTTLE

NDC: 71335-0020-4: 18 Tablets in a BOTTLE

**Store at Controlled Room Temperature 20° - 25°C (68° - 77°F).**

Dispense in a tight, light-resistant container as defined in the USP, using a child-resistant closure.

## **Rx only**

Manufactured by:  
Leading Pharma, LLC  
Fairfield, NJ 07004  
Rev. 04 11/19

**Glycopyrrolate 2mg Tablet**

Packaged by Bryant Ranch Prepack

Burbank, CA 91504

# Glycopyrrolate 2mg Tablet

WHITE ROUND EP;140

LOT 1523487

Keep tightly closed

Compare To

Rubinol 2mg Tablet

Leading Pharma LLC

RX Only

Store at room temp of  
20°-25°C (68°-77°F)

# 30

EXP MM/YY

NDC

7133500201



05442301523487

## GLYCOPYRROLATE

glycopyrrolate tablet

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:71335-0020(NDC:69315-140)
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCOPYRROLATE (UNII: V92S09WP2I) (GLYCOPYRRONIUM - UNII:A14FB57V1D)	GLYCOPYRROLATE	2 mg

### Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	EP;140
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-0020-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2021	
2	NDC:71335-0020-2	90 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2021	
3	NDC:71335-0020-3	28 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2021	
4	NDC:71335-0020-4	18 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090195	09/22/2018	

**Labeler** - Bryant Ranch Prepack (171714327)

**Registrant** - Bryant Ranch Prepack (171714327)

## Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-0020) , RELABEL(71335-0020)

Revised: 12/2021

Bryant Ranch Prepack