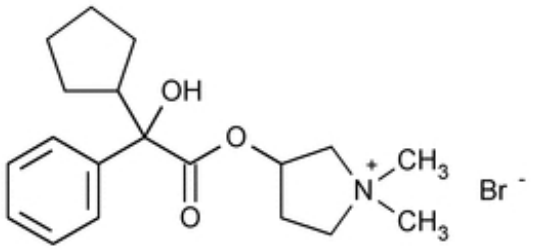
GLYCATE- glycopyrrolate tablet
Nuro Pharma, Inc.

Glycate^{tm} (Glycopyrrolate Tablets, USP) 1.5 mg

DESCRIPTION

Glycopyrrolate Tablets, USP 1.5 mg contains the synthetic anticholinergic, glycopyrrolate. Glycopyrrolate is a quaternary ammonium compound with the following chemical name: 3-[(cyclopentylhydroxyacetyl)oxy]-1,1-dimethylpyrrolidinium bromide.



C19H28BrNO3 MW: 398.33

Each tablet contains:

Glycopyrrolate, USP……..1.5 mg

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

CLINICAL PHARMACOLOGY

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 are non-polar tertiary amines which penetrate lipid barriers easily.

INDICATIONS AND USAGE

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 the use of Glycopyrrolate Tablets, 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 Tablets, USP 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.

PRECAUTIONS

Use Glycopyrrolate Tablets, 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 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.

Interactions

There are no known drug interactions.

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 know 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.

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 Tablets, USP 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.

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 should be adjusted to the needs of the individual patient to assure symptomatic controlwith 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 1 mg tablets 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 2 mg tablets for adults is one tablet two or three times daily at equally spaced intervals.

Glycopyrrolate Tablets, USP 1.5 mg. The Glycopyrrolate 1.5 mg tablets may be used to provide intermediate titration doses based on response of the patient.

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

HOW SUPPLIED

Glycate™ (Glycopyrrolate Tablets, USP) 1.5 mg are compressed white tablets debossed GP on one

side and 1.5 on the other and are supplied in bottles of 100 (NDC 59547-210-19).

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

Keep out ofreach of children.

Dispense in tight container.

Manufactured by:

Nexgen Pharma, Inc.

Irvine, CA 92614

Manufactured for:

Nuro Pharma, Inc.

Las Vegas, NV 89118

Rev. 09/13

7097

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

Glycate™

NDC 59547-210-19

Bottle Label x 100 Tablets

GLYCATE

glycopyrrolate tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59547-210
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

GLYCOPYRROLATE (UNII: V92SO9WP2I) (GLYCOPYRRONIUM - UNII:A14FB57V1D)	GLYCOPYRROLATE	1.5 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM PYROPHOSPHATE (UNII: X69NU20D19)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONES (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND TABLET; DEBOSSED ON BOTH SIDES)	**Size**	9mm
Flavor		**Imprint Code**	GP;15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59547-210-19	100 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091522	03/12/2012	

Labeler - Nuro Pharma, Inc. (054205929)

Registrant - Nuro Pharma, Inc. (054205929)

Establishment

Name	Address	ID/FEI	Business Operations
Nexgen Pharma, Inc		160356114	MANUFACTURE(59547-210) , ANALYSIS(59547-210) , PACK(59547-210) , LABEL(59547-210)

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