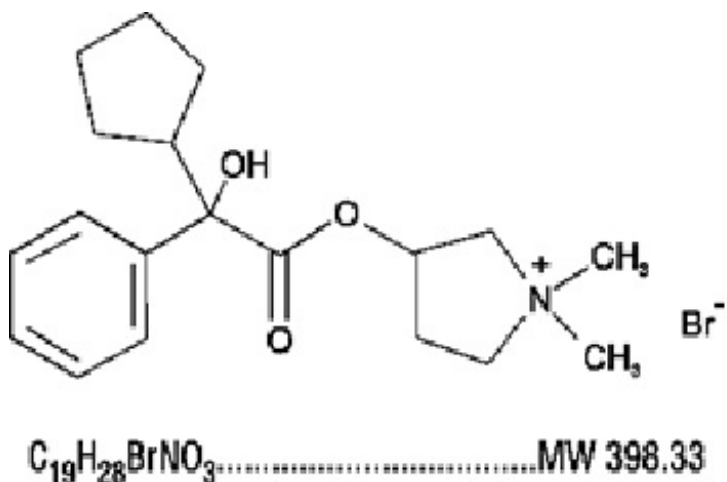


GLYCOPYRROLATE - glycopyrrolate tablet
Aurolife Pharma, LLC

Glycopyrrolate Tablets, USP
Rx only

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 .



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

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

Inactive Ingredients: dibasic calcium phosphate dihydrate, lactose monohydrate, magnesium Stearate, povidone, and 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 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 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 use of glycopyrrolate tablets.

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 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.

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 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 1 mg. The recommended initial dosage of glycopyrrolate 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 2 mg. The recommended dosage of glycopyrrolate tablets 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 white to off-white, round, beveled edge uncoated tablets, debossed with 'Y' and break line on one side and '08' on the other side.

Bottles of 10	NDC 13107-014-11
Bottles of 100	NDC 13107-014-01
Bottles of 1000	NDC 13107-014-99
10 x 10 Unit-dose Tablets	NDC 13107-014-10

Glycopyrrolate Tablets USP, 2 mg are white to off-white, round, beveled edge uncoated tablets, debossed with 'Y' and break line on one side and '51' on the other side.

Bottles of 10	NDC 13107-015-11
Bottles of 100	NDC 13107-015-01
Bottles of 1000	NDC 13107-015-99
10 x 10 Unit-dose Tablets	NDC 13107-015-10

Store at

20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature].

Keep this and all medication out of the reach of children.

Dispense in a tight container.

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Distributed by:

Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Revised: 04/2018

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1 mg (100 Tablet Bottle)

NDC 13107-014-01

Glycopyrrolate Tablets, USP 1 mg

WHITE DYE-FREE

Rx only 100 Tablets

AUROBINDO

Rx only
Glycopyrrolate Tablets, USP
1 mg
WHITE DYE-FREE
AUROBINDO **100 Tablets**

NDC 13107-014-01

Each tablet contains: Glycopyrrolate, USP 1 mg.
Keep this and all medication out of the reach of children.
Usual Dosage: One or two tablets three times a day.
See package Insert for complete prescribing information.
PHARMACIST: Dispense in a tight container.
Store at 20°C to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
Revised: 04/2018

Distributed by:
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

LM-2240

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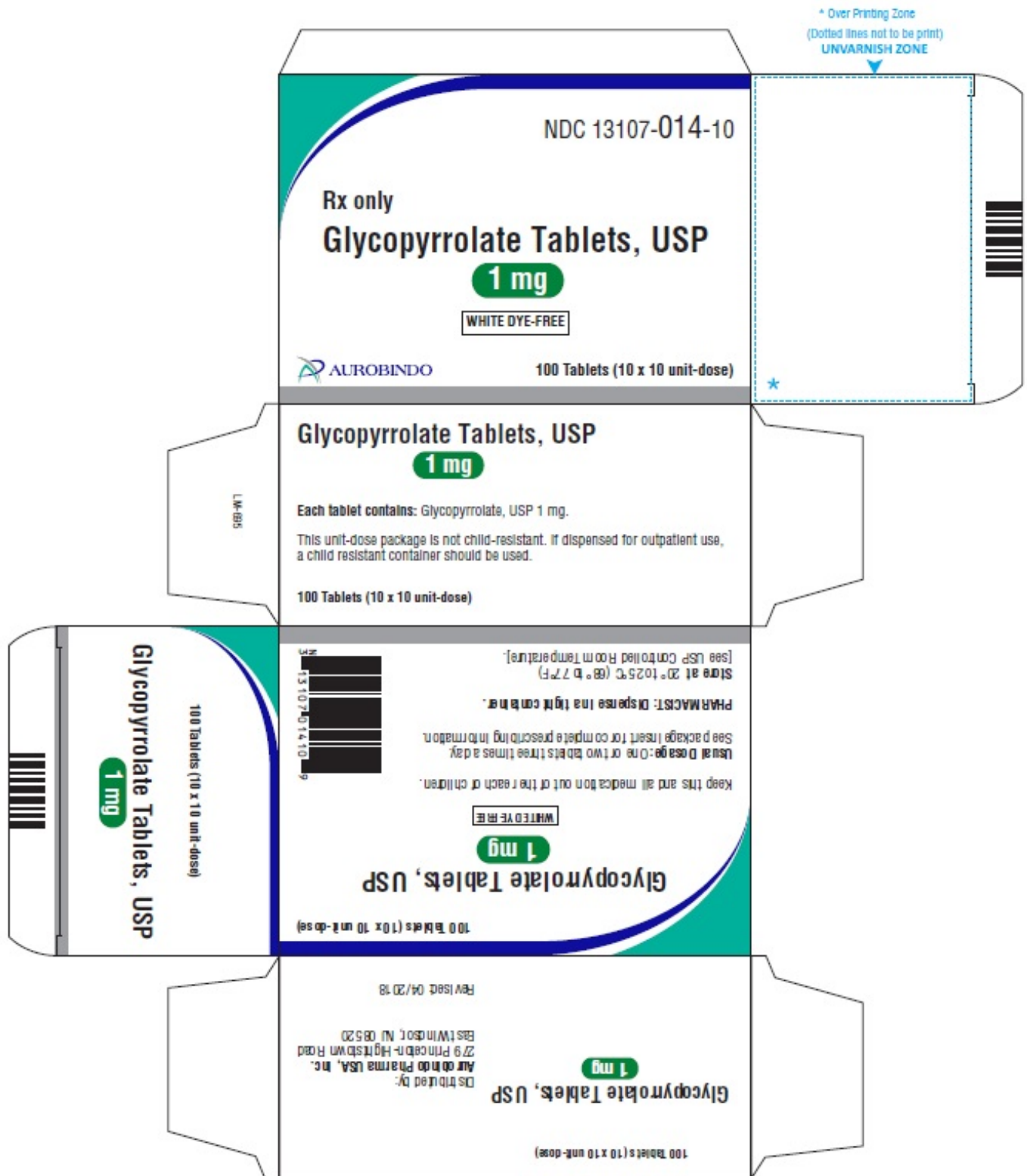
PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1 mg Blister Carton (10 x 10 Unit-dose)

Rx only NDC 13107-014-10 Glycopyrrolate Tablets, USP 1 mg

WHITE DYE-FREE

100 Tablets (10 x 10 unit-dose)

AUROBINDO



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 2 mg (100 Tablet Bottle)

NDC 13107-015-01
Glycopyrrolate Tablets, USP 2 mg
WHITE DYE-FREE
Rx only 100 Tablets
AUROBINDO

NDC 13107-015-01

**Glycopyrrolate
Tablets, USP**

2 mg

WHITE DYE-FREE

Rx only 100 Tablets

AUROBINDO

Each tablet contains:
Glycopyrrolate, USP 2 mg.

Keep this and all medication out of the reach of children.

Usual Dosage: One tablet two or three times a day. See package Insert for complete prescribing information.

PHARMACIST: Dispense in a tight container.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Revised: 04/2018

Distributed by:
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

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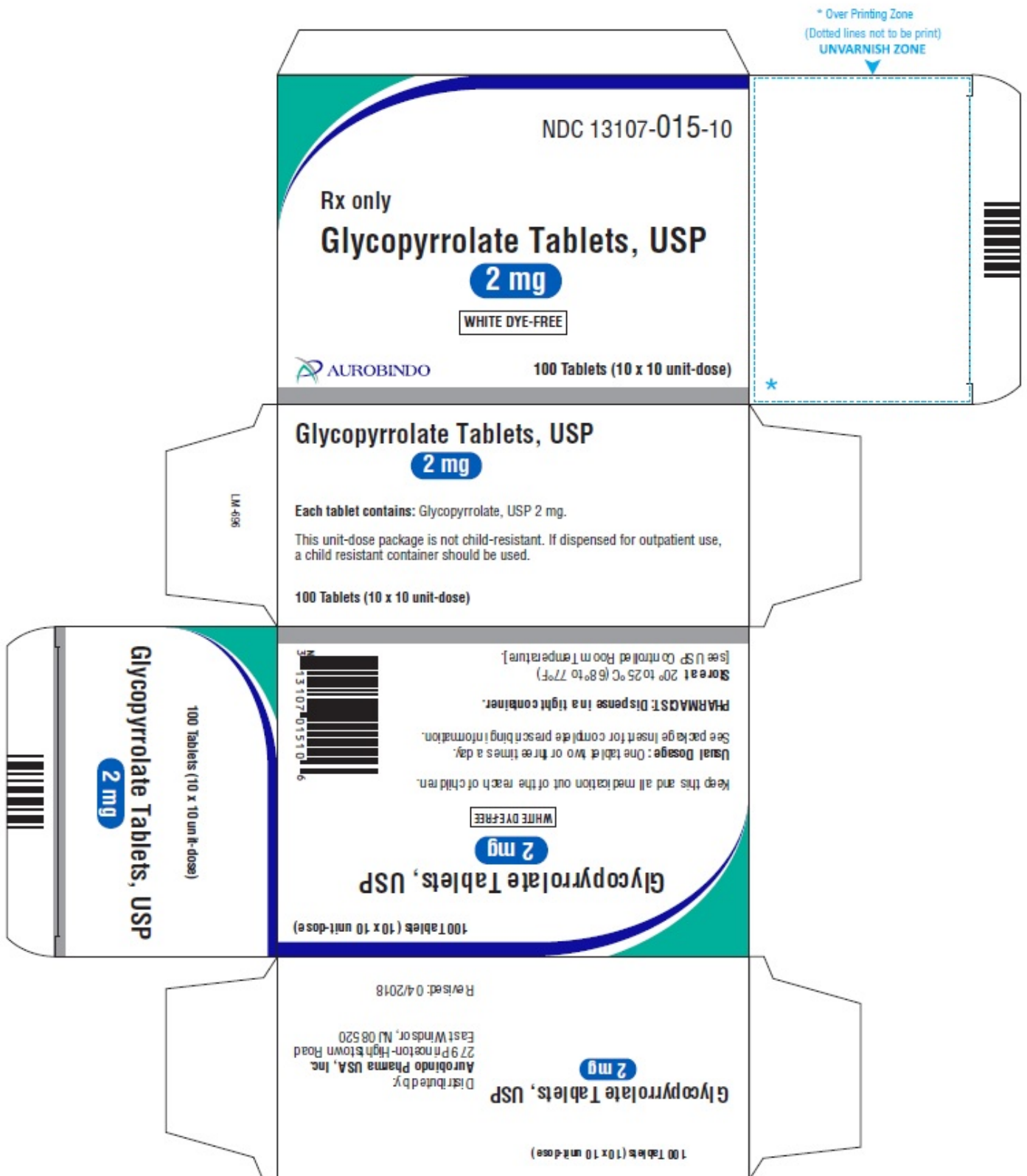
LM-693

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PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 2 mg Blister Carton (10 x 10 Unit-dose)

Rx only NDC 13107-015-10
Glycopyrrolate Tablets, USP 2 mg
WHITE DYE-FREE
100 Tablets (10 x 10 unit-dose)
AUROBINDO

* Over Printing Zone
(Dotted lines not to be print)
UNVARNISH ZONE



GLYCOPYRROLATE

glycopyrrolate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:13107-014
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 MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE (White to Off-white)	Score	2 pieces
Shape	ROUND (Beveled Edge)	Size	8mm
Flavor		Imprint Code	Y;08
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13107-014-11	10 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2013	
2	NDC:13107-014-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2013	
3	NDC:13107-014-99	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2013	
4	NDC:13107-014-10	10 in 1 CARTON	04/15/2013	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202675	04/15/2013	

GLYCOPYRROLATE

glycopyrrolate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:13107-015
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
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	WHITE (White to Off-White)	Score	2 pieces
Shape	ROUND	Size	10mm
Flavor		Imprint Code	Y;51
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13107-015-11	10 in 1 BOTTLE; Type 0: Not a Combination Product	10/30/2018	
2	NDC:13107-015-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/30/2018	
3	NDC:13107-015-99	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/30/2018	
4	NDC:13107-015-10	10 in 1 CARTON	10/30/2018	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202675	10/30/2018	

Labeler - Aurolife Pharma, LLC (829084461)**Establishment**

Name	Address	ID/FEI	Business Operations
Aurolife Pharma, LLC		829084461	MANUFACTURE(13107-014, 13107-015)