

LONHALA- glycopyrrolate solution
Holopack Verpackungstechnik GmbH

Glycopyrrolate Inhalation Solution (25 µg/mL)

Lonhala

(glycopyrrolate) inhalation solution, for oral inhalation use

PRINCIPAL DISPLAY PANEL - SHIPPER LABEL

1 carton = 432 pouches

Glycopyrrolate Inhalation Solution (25 µg/mL)

Item No. 401732-001

Lot: UE076

Exp: 03-2019

Caution: For manufacturing, processing, or repacking.

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

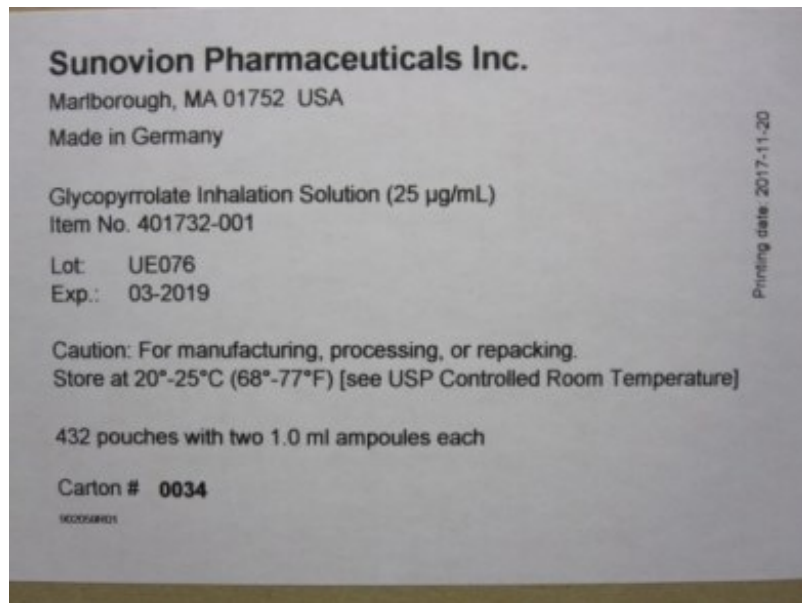
432 pouches with two 1.0 ml ampoules each

Carton # 0034

Made in Germany

Sunovion Pharmaceuticals Inc.

Marlborough, MA 01752 USA



LONHALA

glycopyrrolate solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60940-024
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCOPYRROLATE (UNII: V92SO9WP2I) (GLYCOPYRRONIUM - UNII:A14FB57V1D)	GLYCOPYRROLATE	25 ug in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium Chloride (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60940-024-01	432 in 1 CARTON	12/05/2017	
1		2 in 1 POUCH		
1		1 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208437	12/05/2017	

Labeler - Holopack Verpackungstechnik GmbH (313222457)

Establishment

Name	Address	ID/FEI	Business Operations
Holopack Verpackungstechnik GmbH		343390324	manufacture(60940-024)

Revised: 11/2019

Holopack Verpackungstechnik GmbH