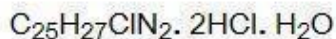
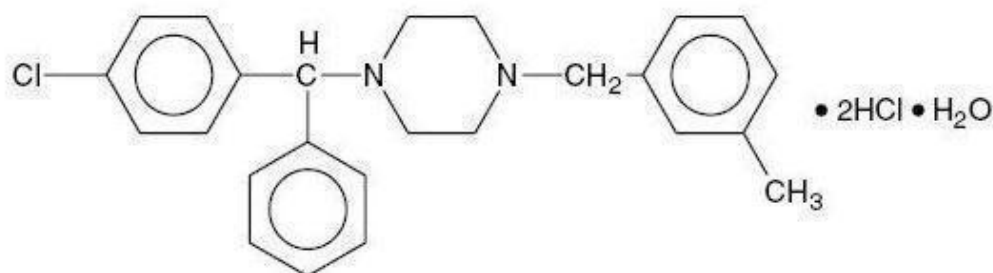


MECLIZINE HYDROCHLORIDE- meclizine hydrochloride tablet DIRECT RX

Meclizine Hydrochloride

DESCRIPTION SECTION

Chemically, Meclizine HCl is 1-(p-chloro- α -phenylbenzyl)-4-(m-methylbenzyl) piperazine dihydrochloride monohydrate.



481.88

M.W.

Meclizine HCl Tablets, USP are available in two different strengths: 12.5 mg and 25 mg. In addition each tablet contains the following inactive ingredients: Colloidal Silicon Dioxide, Croscarmellose Sodium, Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose. Also, Meclizine HCl Tablets USP, 12.5 mg contains FD&C Blue #1 Aluminum Lake (11-13%) and Meclizine HCl Tablets USP, 25 mg contains D&C Yellow #10 Aluminum Lake (15-20%).

CLINICAL PHARMACOLOGY SECTION

Meclizine Hydrochloride is an antihistamine which shows marked protective activity against nebulized histamine and lethal doses of intravenously injected histamine in guinea pigs. It has a marked effect in blocking the vasodepressor response to histamine, but only a slight blocking action against acetylcholine. Its activity is relatively weak in inhibiting the spasmogenic action of histamine on isolated guinea pig ileum.

INDICATIONS & USAGE SECTION

Meclizine Hydrochloride is contraindicated in individuals who have shown a previous hypersensitivity to it

CONTRAINDICATIONS SECTION

Meclizine Hydrochloride is contraindicated in individuals who have shown a previous

hypersensitivity to it

WARNINGS SECTION

Since drowsiness may, on occasion, occur with use of this drug, patients should be warned of this possibility and cautioned against driving a car or operating dangerous machinery.

Patients should avoid alcoholic beverages while taking this drug.

Due to its potential anticholinergic action, this drug should be used with caution in patients with asthma, glaucoma or enlargement of the prostate gland.

PRECAUTIONS SECTION

PREGNANCY, Teratogenic Effects

Pregnancy Category B. Reproduction studies in rats have shown cleft palates at 25-50 times the human dose. Epidemiological studies in pregnant women, however, do not indicate that medicine increases the risk of abnormalities when administered during pregnancy. Despite the animal findings, it would appear that the possibility of fetal harm is remote. Nevertheless, meclizine, or any other medication, should be used during pregnancy only if clearly necessary.

Pediatric Use

Clinical studies establishing safety and effectiveness in children have not been done; therefore, usage is not recommended in children under 12 years of age.

ADVERSE REACTIONS SECTION

Drowsiness, dry mouth and, on rare occasions, blurred vision have been reported.

DOSAGE & ADMINISTRATION SECTION

Motion Sickness

The initial dose of 25 to 50 mg of Meclizine HCl should be taken one hour prior to travel for protection against motion sickness. Thereafter, the dose may be repeated every 24 hours for the duration of the journey.

HOW SUPPLIED SECTION

Meclizine HCl Tablets, USP are available in the following strengths and package sizes:

12.5 mg (Blue, oval-shaped, scored, debossed with TL122)

Bottles of 100 NDC 59746-122-06

Bottles of 1000 NDC 59746-122-10

25 mg (Yellow, oval-shaped, scored, debossed with TL121)

Bottles of 100 NDC 59746-121-06
 Bottles of 1000 NDC 59746-121-10

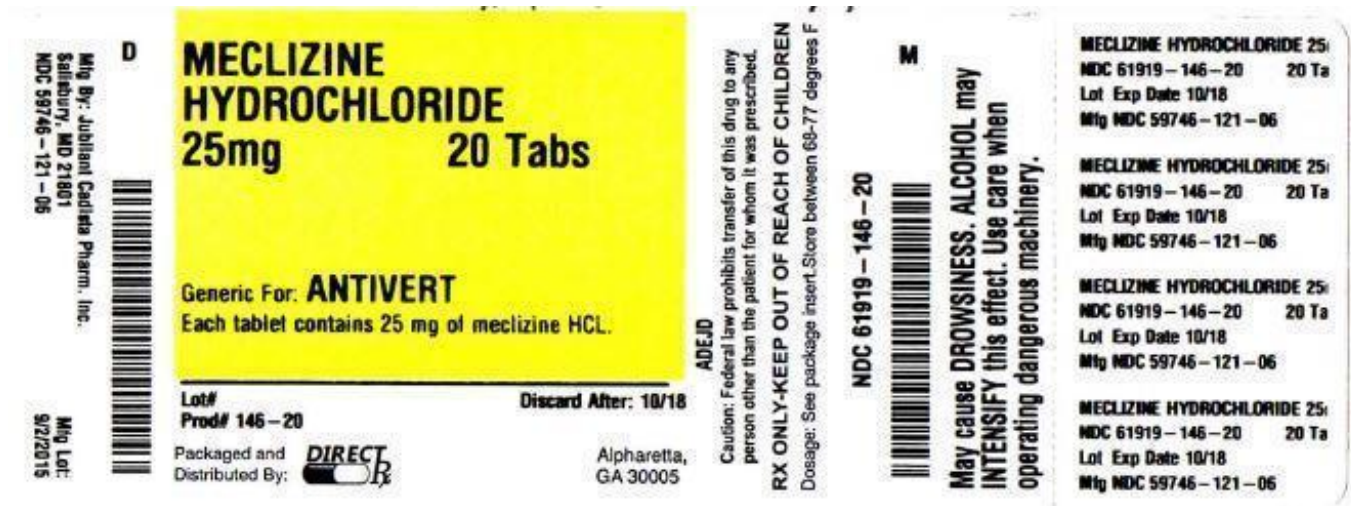
Store at 20-25°C (68-77°F) (See USP Controlled Room Temperature).

Manufactured By:

Jubilant Cadista Pharmaceuticals Inc.
 Salisbury, MD 21801, USA.

Revised 03/11

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:61919-146(NDC:59746-121)
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Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	yellow	Score	2 pieces
Shape	OVAL	Size	13mm
Flavor		Imprint Code	TL121
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-146-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2014	
2	NDC:61919-146-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040659	01/01/2014	

Labeler - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	relabel(61919-146) , repack(61919-146)

