MECLIZINE HYDROCHLORIDE- meclizine hydrochloride tablet
Direct_Rx

MECLIZINE HYDROCHLORIDE

Meclizine HCl, USP an oral antiemetic, is a white or slightly yellowish, crystalline powder. It has the following structural formula:

[Structure of Meclizine HCl]

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

Meclizine hydrochloride 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 hydrochloride tablets USP, 12.5 mg contains FD&C Blue #1 Aluminum Lake (11-13%) and Meclizine hydrochloride tablets USP, 25 mg contains D&C Yellow #10 Aluminum Lake (15-20%).

Each meclizine HCl 12.5 mg tablet contains 12.5 mg of meclizine dihydrochloride equivalent to 10.53 mg of meclizine free base.

Each meclizine HCl 25 mg tablet contains 25 mg of meclizine dihydrochloride equivalent to 21.07 mg of meclizine free base.

Meclizine hydrochloride is an antihistamine that 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.

Pharmacokinetics
The available pharmacokinetic information for meclizine following oral administration has been summarized from published literature.

Absorption
Meclizine is absorbed after oral administration with maximum plasma concentrations reaching at a median Tmax value of 3 hours post-dose (range: 1.5 to 6 hours) for the tablet dosage form.

Distribution
Drug distribution characteristics for meclizine in humans are unknown.

Metabolism
The metabolic fate of meclizine in humans is unknown. In an in vitro metabolic study using human hepatic microsome and recombinant CYP enzyme, CYP2D6 was found to be the dominant enzyme for metabolism of meclizine.

The genetic polymorphism of CYP2D6 that results in extensive-, poor-, intermediate- and ultra-rapid metabolizer phenotypes could contribute to large inter-individual variability in meclizine exposure.

Elimination
Meclizine has a plasma elimination half-life of about 5-6 hours in humans.

Meclizine hydrochloride tablets are indicated for the treatment of vertigo associated with diseases affecting the vestibular system.

Meclizine hydrochloride tablets are contraindicated in individuals who have shown a previous hypersensitivity to it.

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.

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.

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 meclizine 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.

Nursing Mothers
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when meclizine is administered to a nursing woman.

Hepatic Impairment
The effect of hepatic impairment on the pharmacokinetics of meclizine has not been evaluated. As meclizine undergoes metabolism, hepatic impairment may result in increased systemic exposure of the drug. Treatment with meclizine should be administered with caution in patients with hepatic impairment.

Renal Impairment
The effect of renal impairment on the pharmacokinetics of meclizine has not been evaluated. Due to a potential for drug/metabolite accumulation, meclizine should be administered with caution in patients with renal impairment and in the elderly as renal function generally declines with age.

Drug Interactions
There may be increased CNS depression when meclizine is administered concurrently with other CNS depressants, including alcohol, tranquilizers, and sedatives. (see WARNINGS).

Based on in-vitro evaluation, meclizine is metabolized by CYP2D6. Therefore there is a possibility for a drug interaction between meclizine and CYP2D6 inhibitors.

Anaphylactoid reaction, drowsiness, dry mouth, headache, fatigue, vomiting and, on rare occasions, blurred vision have been reported.

To report SUSPECTED ADVERSE REACTIONS, contact Jubilant Cadista Pharmaceuticals Inc. at 1-800-313-4623 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

The recommended dose is 25 to 100 mg daily administered orally, in divided dosage, depending upon clinical response.

Meclizine hydrochloride tablets, USP are available in the following strengths and package sizes:

12.5 mg (Blue, oval shaped tablets, debossed with “TL 122” with score on one side and plain on the other side.)
Bottles of 100
Bottles of 1000

25 mg (Yellow, oval shaped tablets, debossed with “TL 121” with score on one side and plain on the other side.)
Bottles of 100
Bottles of 1000

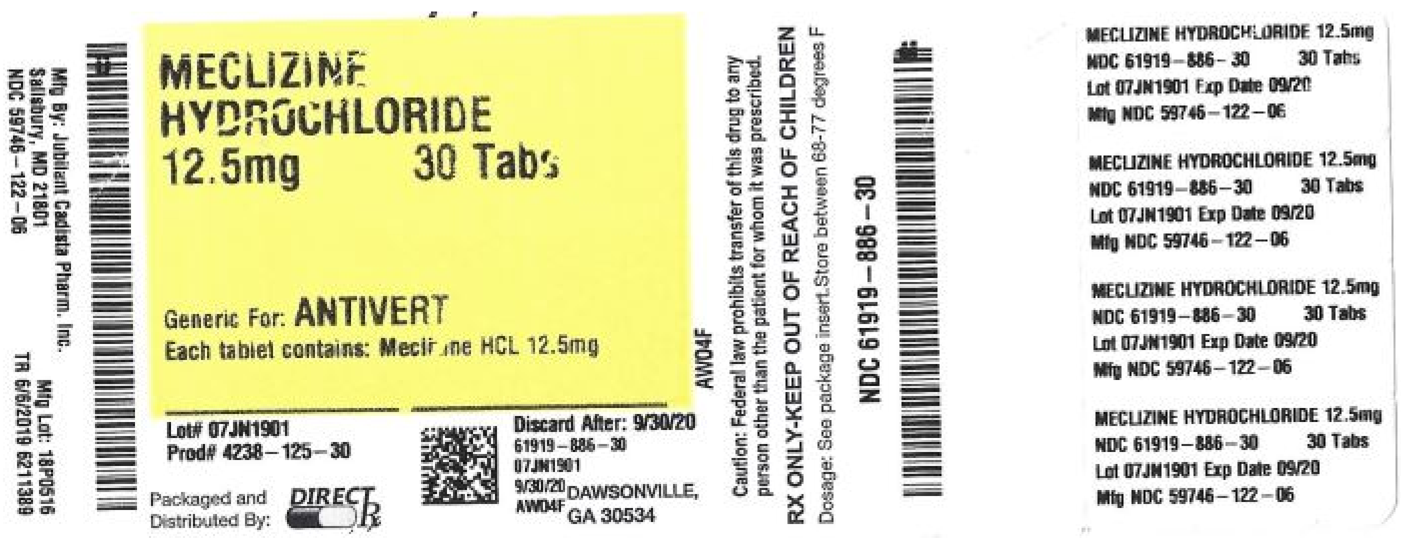
Store at 20 to 25°C (68 to 77°F) [See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container (USP).

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

Manufactured By:
Jubilant Cadista Pharmaceuticals Inc.
Salisbury, MD 21801, USA

Revised 01/2019



MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet

Product Information			
	HUMAN PRESCRIPTION	Item Code	NDC:61919-886(NDC:59746

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61919-886(NDC:59746-122)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	12.5 mg

Inactive Ingredients

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

Product Characteristics

Color	blue	**Score**	2 pieces
Shape	OVAL	**Size**	10mm
Flavor		**Imprint Code**	TL122
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-886-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040659	08/01/2019	

Labeler - Direct_Rx (079254320)

Registrant - Direct_Rx (079254320)

Establishment

Name	Address	ID/FEI	Business Operations

Direct_Rx		079254320	repack(61919-886)