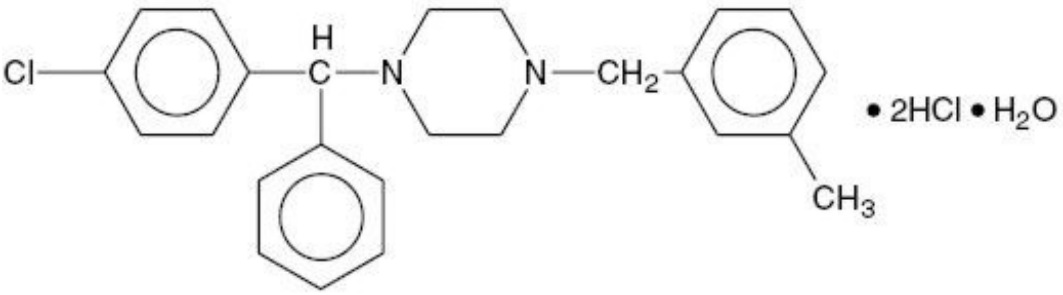
MECLIZINE HYDROCHLORIDE- meclizine hydrocloride tablet
NuCare Pharmaceuticals,Inc.

Meclizine hydrochloride tablets, USP

Rx Only

DESCRIPTION

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



$C_{25}H_{27}ClN_2 \bullet 2HCl \bullet H_2O$ Molecular Weight 481 **.**88

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%).

CLINICAL PHARMACOLOGY

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 T_{max} 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.

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

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

WARNINGS

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

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
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.

ADVERSE REACTIONS

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.

DOSAGE AND ADMINISTRATION

For the treatment of vertigo associated with diseases affecting the vestibular system, the recommended dose is 25 to 100 mg daily, in divided dosage, depending upon clinical response.

HOW SUPPLIED

25 mg (Yellow, oval shaped tablets, debossed with TL 121 with score on one side and plain on the other side.)

NDC 68071-4694-4 BOTTLES OF 4
NDC 68071-4694-6 BOTTLES OF 6

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

Manufactured By:

Jubilant Cadista Pharmaceuticals Inc.

Salisbury, MD 21801, USA

Revised 05/2018

PRINCIPAL DISPLAY PANEL

MECLIZINE HYDROCHLORIDE

meclizine hydrocloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68071-4694(NDC:59746-121)
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

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:68071-4694-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/07/2019	
2	NDC:68071-4694-4	4 in 1 BOTTLE; Type 0: Not a Combination Product	01/07/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040659	06/04/2010	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	repack(68071-4694)

Revised: 1/2022 NuCare Pharmaceuticals,Inc.