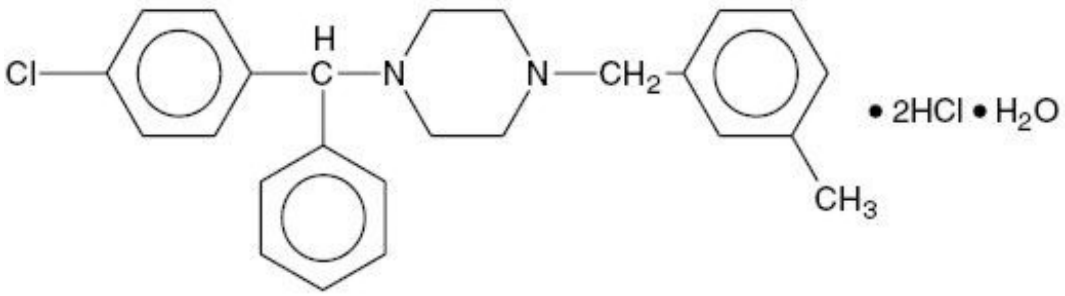
MECLIZINE HYDROCHLORIDE - meclizine hydrocloride tablet
H.J. Harkins Company, Inc.

MECLIZINE HYDROCHLORIDE TABLETS, USP
Rx only

DESCRIPTION

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



$C_{25}H_{27}ClN_2$**.** 2HCl**.** H_2O M**.**W**.** 481**.**88

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

CLINICAL PHARMACOLOGY

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 AND USAGE

For the management of nausea and vomiting, and dizziness associated with motion sickness.

CONTRAINDICATIONS

Meclizine Hydrochloride is 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

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

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

DOSAGE AND ADMINISTRATION

Motion Sickness
The initial dose of 25 to 50 mg of Meclizine HCI 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

Meclizine HCI 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

Repacked by:

H.J. Harkins Company, Inc.
513 Sandydale Drive
Nipomo, CA 93444

PRINCIPAL DISPLAY PANEL

NDC 59746-121-010

CADISTA

Meclizine Hydrochloride Tablets, USP

25 mg

Rx only

1000 Tablets

Each tablet contains 25 mg of meclizine HCl.

DOSAGE AND USE
See accompanying prescribing information

MOTION SICKNESS:
25 mg to 50 mg daily.

Dispense in tight, light-resistant containers (USP).

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

Jubilant Cadista Pharmaceuticals Inc.
Salisbury, MD 21801, USA

Repacked by:

H.J. Harkins Company, Inc.

Nipomo, CA 93444
Rev.# 03/11

Lot No.:

Exp Date:

MECLIZINE HYDROCHLORIDE

meclizine hydrocloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:52959-033(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:52959-033-04	4 in 1 BOTTLE		
2	NDC:52959-033-10	10 in 1 BOTTLE		

3	NDC:52959-033-15	15 in 1 BOTTLE		
4	NDC:52959-033-20	20 in 1 BOTTLE		
5	NDC:52959-033-21	21 in 1 BOTTLE		
6	NDC:52959-033-25	25 in 1 BOTTLE		
7	NDC:52959-033-30	30 in 1 BOTTLE		
8	NDC:52959-033-60	60 in 1 BOTTLE		
9	NDC:52959-033-90	90 in 1 BOTTLE		
10	NDC:52959-033-00	100 in 1 BOTTLE		

Marketing Information

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

Labeler - H.J. Harkins Company, Inc. (147681894)

Establishment

Name	Address	ID/FEI	Business Operations
JUBILANT CADISTA PHARMACEUTICALS, INC.		022490515	MANUFACTURE

Revised: 2/2012 H.J. Harkins Company, Inc.