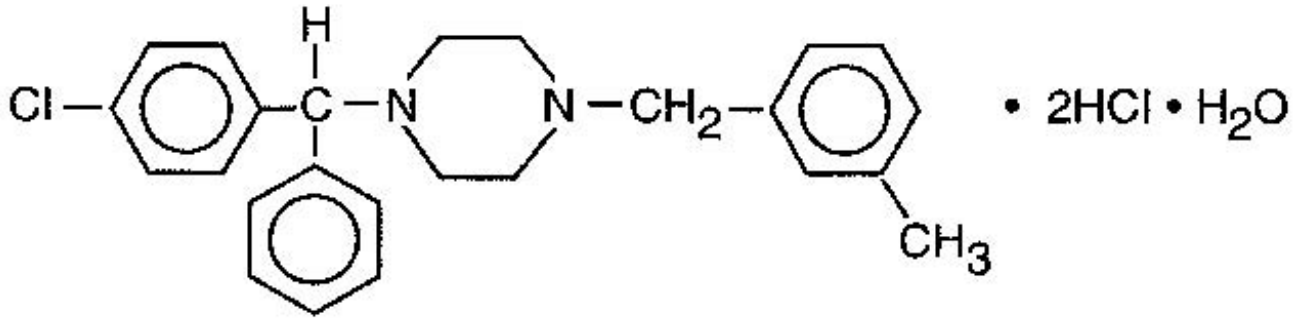
MECLIZINE HYDROCHLORIDE - meclizine hydrochloride tablet
H.J. Harkins Company, Inc.

DESCRIPTION

Meclizine hydrochloride, an oral antiemetic, is a white, slightly yellowish, crystalline powder which has a slight odor and is tasteless. It has the following structural formula:



$C_{25}H_{27}ClN_2 \cdot 2HCl \cdot H_2O$ M.W. 481.89

The chemical name is 1-(*p*-chloro-alpha-phenylbenzyl)-4-(*m*-methyl-benzyl) - piperazine dihydrochloride monohydrate.

Meclizine Hydrochloride Tablets are available in 12.5 mg, and *25 mg strengths for oral administration.

*Contains FD&C Yellow #5 (see PRECAUTIONS).

Each tablet contains the following inactive ingredients: colloidal silicon dioxide, lactose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, starch, and stearic acid. In addition, the 12.5 mg tablet contains FD&C Blue #1; and the 25 mg tablet contains D&C Yellow #10 and FD&C Yellow #5.

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 prevention and treatment of nausea, vomiting, or 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 the 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. Do not give to children under 12 years of age unless directed by a doctor.

PRECAUTIONS

The Meclizine Hydrochloride Tablets, 25 mg contain FD&C Yellow #5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD&C Yellow #5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

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

Usage in 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 hydrochloride 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 hydrochloride, or any other medication should be used during pregnancy only if clearly necessary.

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 meclizine hydrochloride, 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 Hydrochloride Tablets, USP 12.5 mg - blue, oval tablets debossed with “034” on one side and “par” on the other side. Tablets may contain characteristic dye spots. They are supplied in bottles of 100 (NDC 49884-034-01) and 1000 (NDC 49884-034-10).

Meclizine Hydrochloride Tablets, USP 25 mg - yellow, oval tablets debossed with “035” on one side and “par” on the other side. They are supplied in bottles of 100 (NDC 49884-035-01) and 1000 (NDC 49884-035-10).

Dispense in tight, light-resistant containers as defined in the USP.

Store at controlled room temperature 15°-30°C (59°-86°F).

Manufactured by:

PAR PHARMACEUTICAL COMPANIES, INC.

Spring Valley, NY 10977

Repacked by:

H.J. Harkins Company, Inc.

Nipomo, CA 93444

Revised: 11/11

OS034-01-1-11

PRINCIPAL DISPLAY PANEL: 12.5 MG CONTAINER LABEL 100 TABLETS

MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:52959-225(NDC:49884-034)
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**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics			
Color	BLUE	**Score**	no score
Shape	OVAL	**Size**	5mm
Flavor		**Imprint Code**	Par;034
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52959-225-00	100 in 1 BOTTLE		
2	NDC:52959-225-07	7 in 1 BOTTLE		
3	NDC:52959-225-12	12 in 1 BOTTLE		
4	NDC:52959-225-20	20 in 1 BOTTLE		
5	NDC:52959-225-21	21 in 1 BOTTLE		
6	NDC:52959-225-30	30 in 1 BOTTLE		
7	NDC:52959-225-60	60 in 1 BOTTLE		
8	NDC:52959-225-90	90 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA087127	06/03/1981	

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

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

Establishment

Name	Address	ID/FEI	Business Operations
H.J. Harkins Company, Inc.		147681894	repack, relabel

Revised: 1/2012 H.J. Harkins Company, Inc.