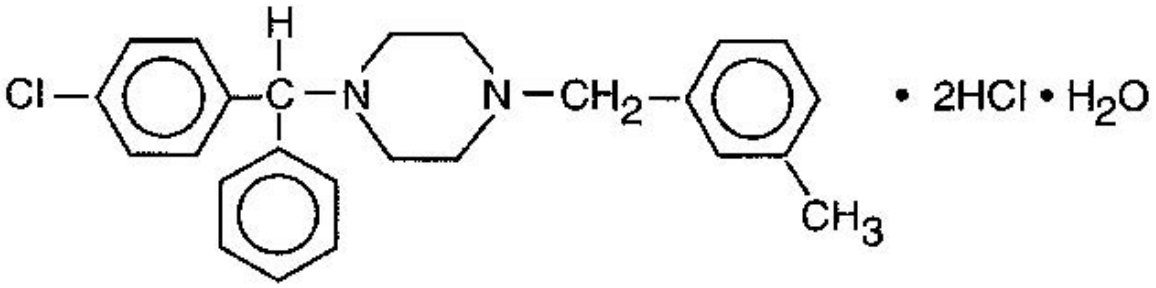
MECLIZINE HYDROCHLORIDE- meclizine hydrochloride tablet
Unit Dose Services

Rx Only

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.

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 in unknown.

Metabolism

The metabolic fate of meclizine in humans in unknown. In an i*n 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 ultrarapid metabolizer phenotypes could contribute to large inter-individual variability in meclizine exposure.

Elimination

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

INDICATIONS AND USAGE

INDICATIONS

Based on a review of this drug by the National Academy of Sciences – National Research Council and/or other information, FDA has classified the indications as follows:

Effective: Management of nausea and vomiting, and dizziness associated with motion sickness.

Possibly Effective: Management of vertigo associated with diseases affecting the vestibular system.

Final classification of the less than effective indications required further investigation.

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.

Usage in Children

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

Usage in Pregnancy

Pregnancy Category B. Reproduction studies in rats have shown cleft palates at 25 to 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.

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.

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 pharmacokinetic 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.

DOSAGE AND ADMINISTRATION

Vertigo

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

***Motion Sickness*:** The initial dose of 25 to 50 mg meclizine hydrochloride, should be taken one hour prior to embarkation for protection against motion sickness. Thereafter, the dose may be repeated every 24 hours for the duration of the journey.

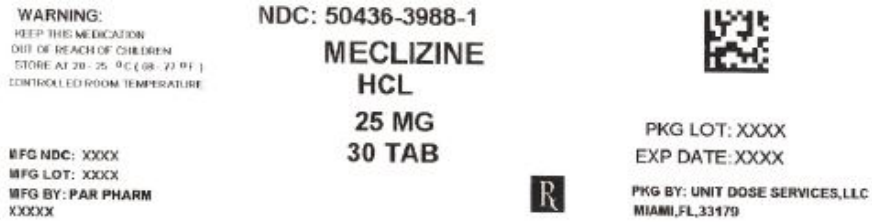
HOW SUPPLIED

Product: 50436-3988

NDC: 50436-3988-1 30 TABLET in a BOTTLE

NDC: 50436-3988-3 90 TABLET in a BOTTLE

MECLIZINE HYDROCHLORIDE (MECLIZINE HYDROCHLORIDE) TABLET



MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:50436-3988(NDC:49884-035)
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
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics			
Color	YELLOW	**Score**	no score
Shape	OVAL	**Size**	6mm
Flavor		**Imprint Code**	Par;035
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50436-3988-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/03/1981	
2	NDC:50436-3988-3	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/03/1981	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA087128	06/03/1981	

Labeler - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-3988) , RELABEL(50436-3988)

Revised: 11/2017 Unit Dose Services