MECLIZINE HYDROCHLORIDE- meclizine hydrochloride tablet
DirectRX

MECLIZINE HYDROCHLORIDE

DESCRIPTION SECTION

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

Chemical Structure

C25H27CIN2·2HCl·H20 M.W. 481.89

Meclizine hydrochloride tablets, USP are available in two different strengths, 12.5 mg and 25 mg. Inactive ingredients: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium and magnesium stearate. The 12.5 mg tablet also contains FD&C Blue #1 Aluminum Lake.

CLINICAL PHARMACOLOGY SECTION

- 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, CYP 2D6 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 5-6 hours in humans.

INDICATIONS & USAGE SECTION

- 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.
  Final classification of the less than effective indications requires further investigation.

CONTRAINDICATIONS SECTION

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

WARNINGS SECTION

- 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.
  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 25-50 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 SECTION

- 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 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 Interactons
  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 SECTION

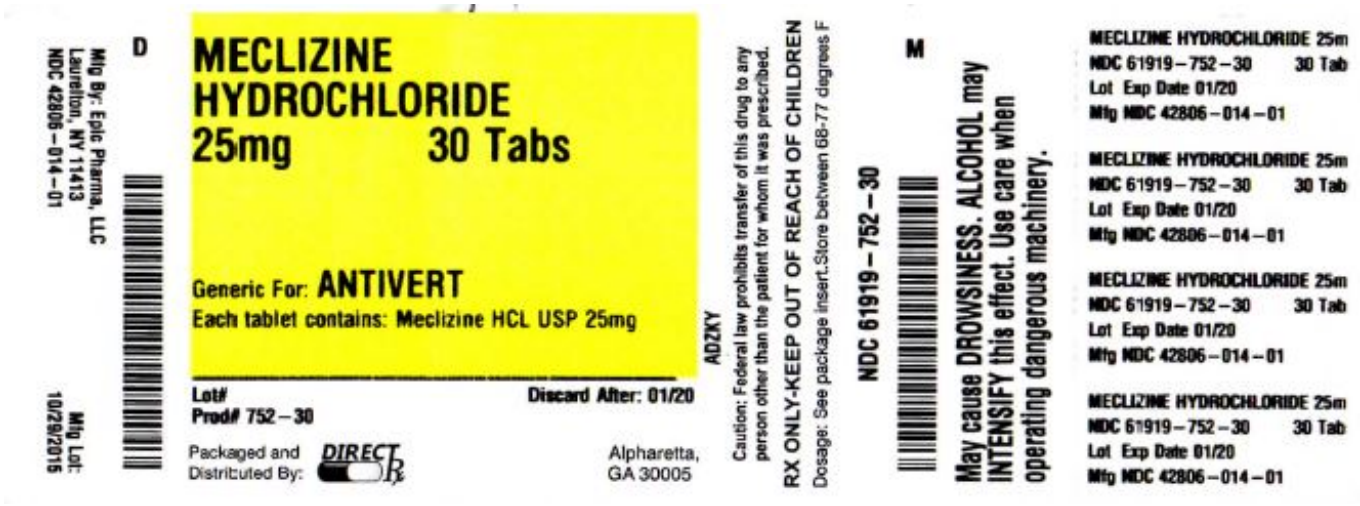
Anaphylactoid reaction, drowsiness, dry mouth, headache, fatigue, vomiting and, on rare occasions, blurred vision have been reported.

DOSAGE & ADMINISTRATION SECTION

Motion Sickness

The initial dose of 25 to 50 mg of 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.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61919-752(NDC:42806-014)
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**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics			
Color	white	**Score**	no score
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	E14
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61919-752-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA200294	01/01/2015	

Labeler - DirectRX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DirectRX		079254320	repack(61919-752)

Revised: 10/2015 DirectRX