MECLIZINE- meclizine tablet
DIRECT RX

MECLIZINE HYDROCHLORIDE 12.5mg 30

DESCRIPTION

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

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

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

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.

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

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

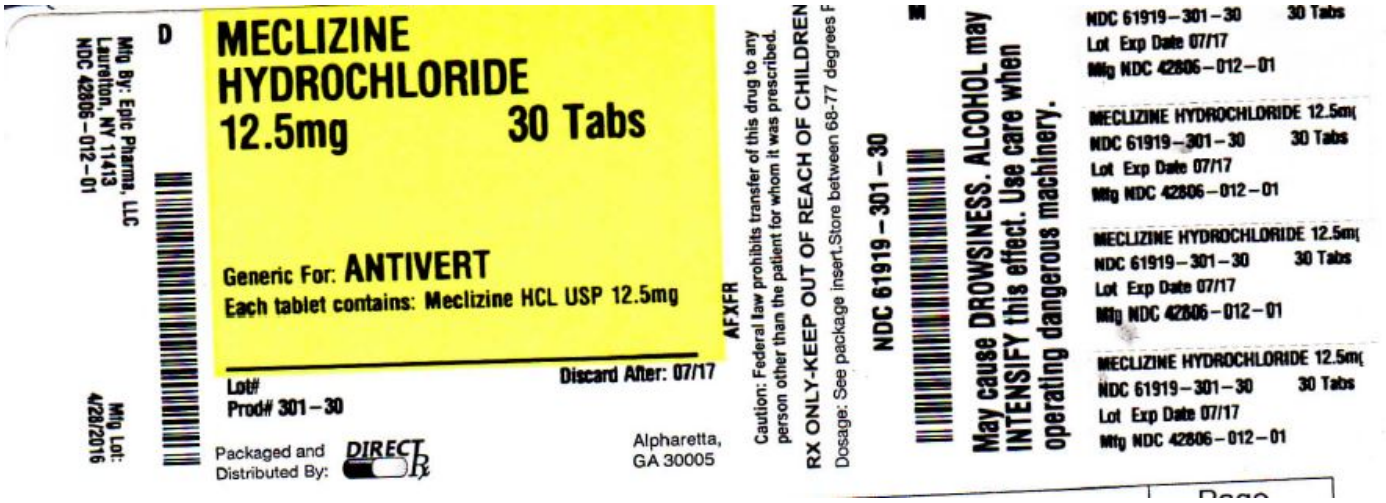
Anaphylactoid reaction, drowsiness, dry mouth, headache, fatigue, vomiting and, on rare occasions, blurred vision have been reported.

DOSAGE AND ADMINISTRATION

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.

PRINCIPAL DISPLAY PANEL



MECLIZINE

meclizine tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61919-301(NDC:42806-012)
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**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL	**Size**	10mm
Flavor		**Imprint Code**	E12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-301-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/28/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA200294	04/28/2016	

Labeler - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	repack(61919-301)

Revised: 1/2020 DIRECT RX