

IH55051016

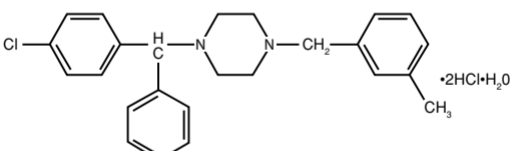
Meclizine HCl Tablets, USP

Rx Only
Rev. 10-2015-00

Meclizine HCl Tablets, USP

DESCRIPTION

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



Inactive ingredients for the tablets are: colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate and talc. The 12.5 mg tablets also contain FD&C Blue #1 Aluminum Lake. The 25 mg tablets also contain D&C Yellow #10 Aluminum Lake.

CLINICAL PHARMACOLOGY

Meclizine HCl 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 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 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, 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

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

CONTRAINDICATIONS

Meclizine HCl, USP 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

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.

Pregnancy Use

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.

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 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

Motion Sickness

The initial dose of 25 mg to 50 mg of meclizine HCl tablets, USP 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 HCl Tablets, USP **12.5 mg**, are supplied as light blue colored, oval shaped tablets with "AN 441" debossed on one side and plain on the other side. They are available as follows:

Bottles of 30:	NDC 65162-441-03
Bottles of 100:	NDC 65162-441-10
Bottles of 500:	NDC 65162-441-50
Bottles of 1000:	NDC 65162-441-11
Blister packs:	NDC 65162-441-60

(Packages of 100 unit doses, 10 cards of 10 tablets each)

Meclizine HCl Tablets, USP **25 mg**, are supplied as light yellow colored, oval shaped tablets with "AN 442" debossed on one side and plain on the other side. They are available as follows:

Bottles of 30:	NDC 65162-442-03
Bottles of 100:	NDC 65162-442-10
Bottles of 500:	NDC 65162-442-50
Bottles of 1000:	NDC 65162-442-11
Blister packs:	NDC 65162-442-60

(Packages of 100 unit doses, 10 cards of 10 tablets each)

Meclizine HCl Tablets, USP **50 mg**, are supplied as white, oval shaped, partially bisected tablets with "AN 444" debossed on one side and plain on the other side. They are available as follows:

Bottles of 30:	NDC 65162-444-03
Bottles of 100:	NDC 65162-444-10
Bottles of 500:	NDC 65162-444-50
Bottles of 1000:	NDC 65162-444-11
Blister packs:	NDC 65162-444-60

(Packages of 100 unit doses, 10 cards of 10 tablets each)

Meclizine HCl Tablets, USP 12.5 mg are distributed by Major® Pharmaceuticals in cartons of 100 tablets, NDC 0904-6516-61

Meclizine HCl Tablets, USP 25 mg are distributed by Major® Pharmaceuticals in cartons of 100 tablets, NDC 0904-6517-61

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container.

Rx only

Distributed by:

Amneal Pharmaceuticals
Bridgewater, NJ 08807

Distributed By:

MAJOR® PHARMACEUTICALS
17177 N Laurel Park Dr., Suite 233
Livonia, MI 48152

Rev. 10-2015-00

IH55051016