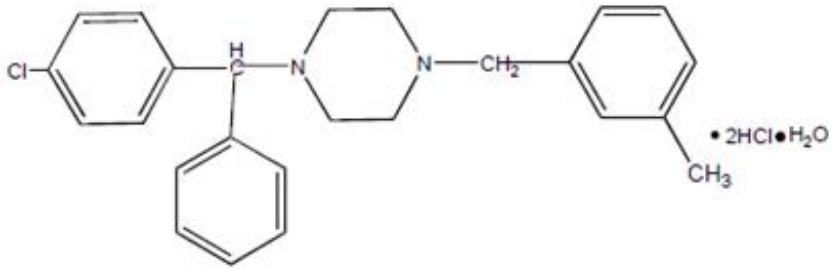
MECLIZINE HYDROCHLORIDE- meclizine tablet
NCS HealthCare of KY, Inc dba Vangard Labs

Meclizine Hydrochloride Tablets, USP
(12.5 mg, 25 mg and 50 mg)
Rx only

DESCRIPTION

Meclizine hydrochloride, USP, an oral antiemetic, is a white or slightly yellowish, crystalline powder. It has the following structural formula:



Chemically, meclizine hydrochloride, 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.

Each meclizine hydrochloride 12.5 mg tablet contains 12.5 mg of meclizine dihydrochloride equivalent to 10.53 mg of meclizine free base.

Each meclizine hydrochloride 25 mg tablet contains 25 mg of meclizine dihydrochloride equivalent to 21.07 mg of meclizine free base.

Each meclizine hydrochloride 50 mg tablet contains 50 mg of meclizine dihydrochloride equivalent to 42.14 mg of meclizine free base.

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 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

Meclizine hydrochloride tablets are indicated for the treatment of vertigo associated with diseases affecting the vestibular system.

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.

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

Teratogenic Effects

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.

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Pharmaceuticals at 1-877-835-5472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

The recommended dosage is 25 mg to 100 mg daily administered orally, in divided dosage, depending upon clinical response.

HOW SUPPLIED

Meclizine Hydrochloride 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:

Blistercards of 30: NDC 0615-8303-39

Meclizine Hydrochloride 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.

Meclizine Hydrochloride 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.

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

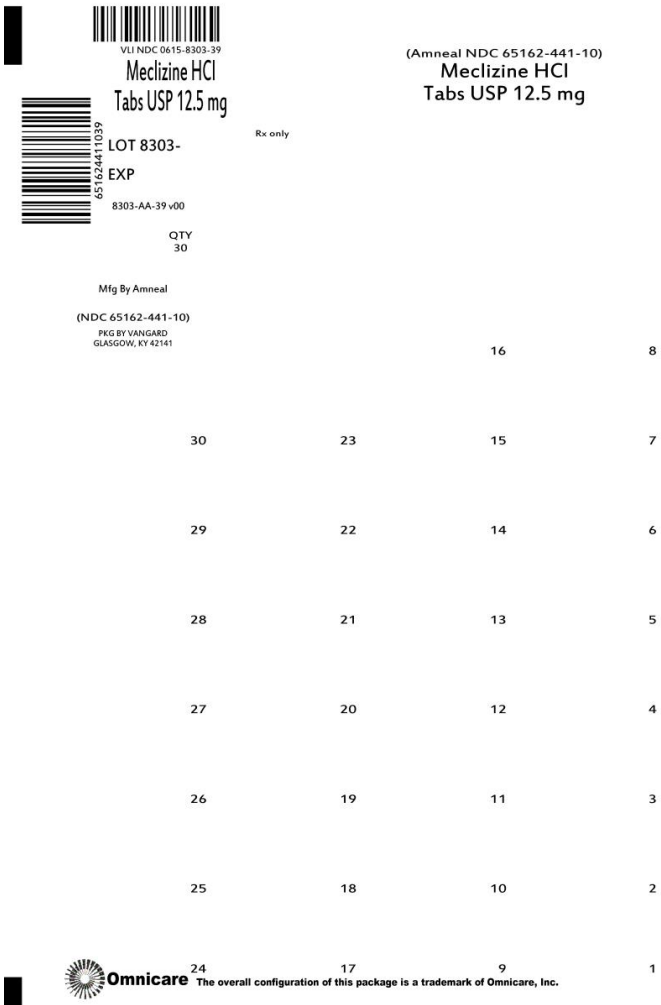
Dispense in a tight, light-resistant container as defined in the USP.

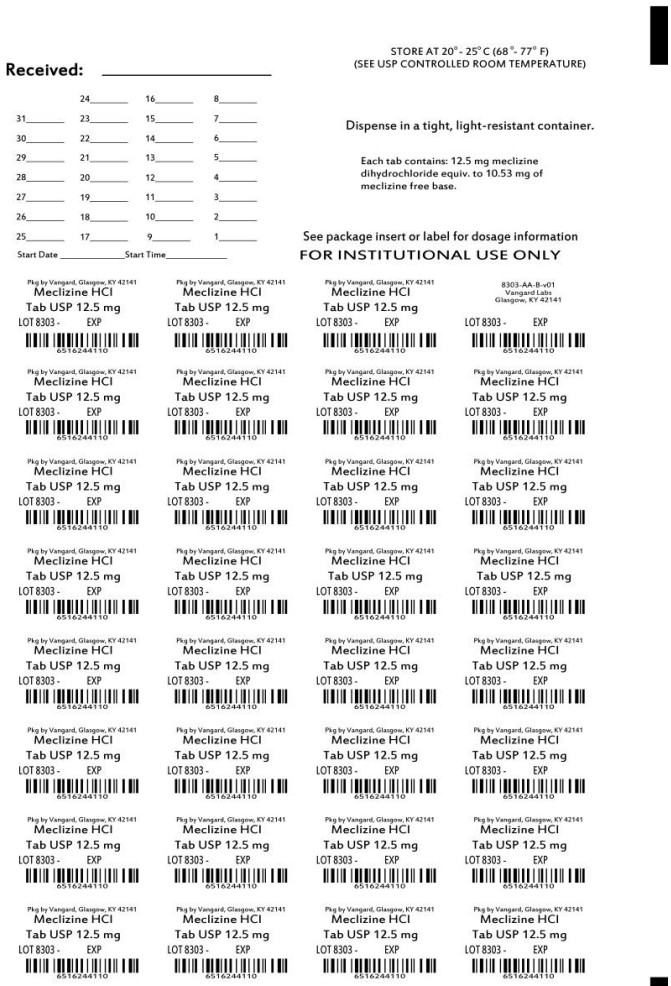
Keep this and all medication out of the reach of children.

Distributed by:
Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807

Rev. 02-2019-03

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





MECLIZINE HYDROCHLORIDE

meclizine tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0615-8303(NDC:65162-441)
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics			
Color	BLUE (Light)	**Score**	no score
Shape	OVAL	**Size**	10mm
Flavor		**Imprint Code**	AN;441
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0615-8303-39	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	07/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA201451	02/12/2010	

Labeler - NCS HealthCare of KY, Inc dba Vangard Labs (050052943)

Establishment

Name	Address	ID/FEI	Business Operations
NCS HealthCare of KY, Inc dba Vangard Labs		050052943	REPACK(0615-8303)

Revised: 12/2019 NCS HealthCare of KY, Inc dba Vangard Labs