MECLIZINE HYDROCHLORIDE- meclizine hydrochloride tablet
Direct_Rx

MECLIZINE HYDROCHLORIDE

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

2.1 Recommended Dosage

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

2.2 Administration Instructions

Tablets

Meclizine hydrochloride tablets must be swallowed whole.

12.5 mg: light blue colored, oval shaped tablets with “AN 441” debossed on one side and plain on the other side.
25 mg: light yellow colored, oval shaped tablets with “AN 442” debossed on one side and plain on the other side.
50 mg: white, oval shaped, partially bisected tablets with “AN 444” debossed on one side and plain on the other side.

Meclizine hydrochloride tablets are contraindicated in patients with a hypersensitivity to meclizine or any of the inactive ingredients [see Adverse Reactions (6) and Description (11)].

5.1 Drowsiness

Since drowsiness may occur with use of meclizine hydrochloride, patients should be warned of this possibility and cautioned against driving a car or operating dangerous machinery.

Patients should avoid alcoholic beverages while taking meclizine hydrochloride [see Drug Interactions (7.1)].

5.2 Concurrent Medical Conditions

Because of its potential anticholinergic action, meclizine hydrochloride should be used with caution in patients with asthma, glaucoma, or enlargement of the prostate gland.

The following adverse reactions associated with the use of meclizine hydrochloride were identified in clinical studies or postmarketing reports. Because some of these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Anaphylactic reaction, drowsiness, dry mouth, headache, fatigue, and vomiting. On rare occasions blurred vision has been reported.

7.1 CNS Depressants

There may be increased CNS depression when meclizine hydrochloride is administered concurrently with other CNS depressants, including alcohol [see Warnings and Precautions (5.1)].

7.2 CYP2D6 Inhibitors

Based on in-vitro evaluation, meclizine is metabolized by CYP2D6. Therefore, there is a possibility for a drug interaction between meclizine hydrochloride and CYP2D6 inhibitors. Therefore, monitor for adverse reactions and clinical effect accordingly.

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Meclizine hydrochloride, a histamine (H1) receptor antagonist, is a white or slightly yellowish, crystalline powder. It has the following structural formula:

[1]

Chemically, meclizine hydrochloride 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.

12.1 Mechanism of Action

The precise mechanism by which meclizine exerts its therapeutic effect is unknown but is presumed to involve antagonism of the histamine H1 receptor.

12.2 Pharmacodynamics

There are no relevant pharmacodynamic data regarding meclizine.

12.3 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.

Elimination

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

Metabolism 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.

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Animal studies to assess the carcinogenic potential of meclizine have not been conducted.

Mutagenesis

Genetic toxicology studies of meclizine have not been conducted.

Impairment of Fertility

Animal studies to assess the effects of meclizine on fertility and early embryonic development have not been conducted.

16.1 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:

Bottles of 30:

Bottles of 100:

Bottles of 500:

Bottles of 1000:

Blister packs:

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

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.

They are available as follows:

Bottles of 30:

Bottles of 100:

Bottles of 500:

Bottles of 1000:

Blister packs:

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

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.

They are available as follows:

Bottles of 30:

Bottles of 100:

Bottles of 500:

Bottles of 1000:

Blister packs:

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

16.2 Storage and Handling

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.

Administration Instructions

Advise patients that the tablets must be swallowed whole [see Dosage and Administration (2.1)].

Adverse Reactions

Advise patients that meclizine hydrochloride may cause anaphylactic reaction, drowsiness, dry mouth, headache, fatigue, vomiting and, on rare occasions, blurred vision [see Warnings and Precautions (5.1), Adverse Reactions (6)].

Inform patients that meclizine hydrochloride may impair their ability to engage in potentially dangerous activities, such as operating machinery or vehicles.

Concomitant Drug Interactions

Advise patients regarding medications that should not be taken in combination with meclizine hydrochloride or that may necessitate increased monitoring [see Drug Interactions (7.1, 7.2)]. Inform patients that alcohol may increase adverse reactions.

Concurrent Medical Conditions

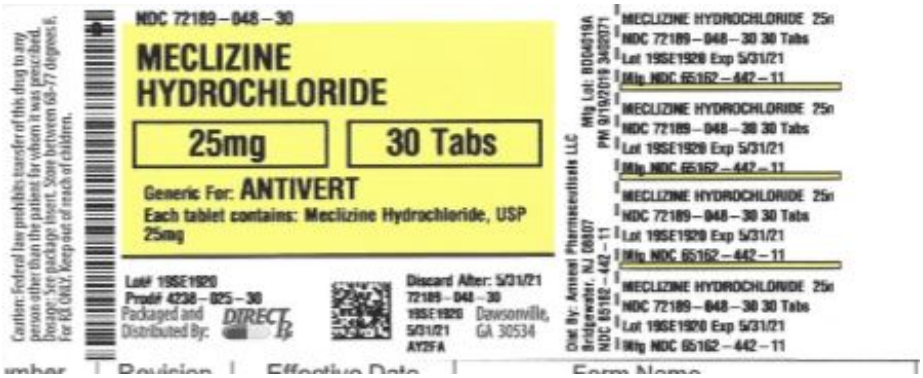
Advise patients to notify their healthcare provider about all of their medical conditions, including if they are pregnant or plan to become pregnant or if they are breastfeeding [see Warnings and Precautions (5.2), Use in Specific Populations (8.1, 8.2)].

Distributed by:

Amneal Pharmaceuticals LLC

Bridgewater, NJ 08807

Rev. 07-2019-04



MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72189-048(NDC:65162-442)
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics

Color	yellow ((Light))	**Score**	no score
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	AN;442
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72189-048-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA201451	09/19/2019	

Labeler - Direct_Rx (079254320)

Registrant - Direct_Rx (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
Direct_Rx		079254320	repack(72189-048)

Revised: 9/2019 Direct_Rx