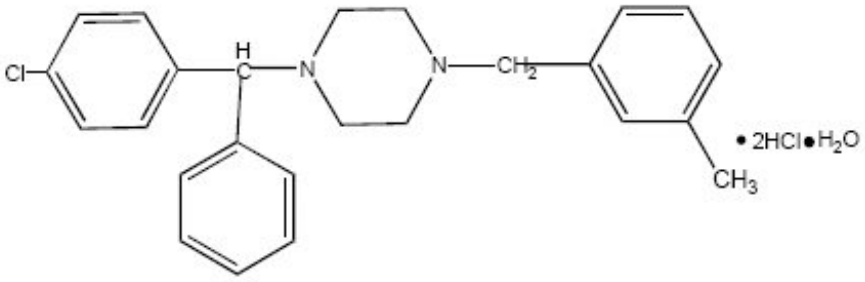
MECLIZINE HYDROCHLORIDE- meclizine hydrochloride tablet
Apotheca Inc.

Meclizine Hydrochloride Tablets USP, 25 mg

Rx Only

DESCRIPTION

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



$C_{25}H_{27}ClN_2 \cdot 2HCl \cdot H_20$ 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 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, 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 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 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.

HOW SUPPLIED

25 mg, white, modified oval-shaped tablets, de-bossed " **€14**" on one side and plain on the other side. They are supplied as follows:

NDC 12634-424-00 Bottles of 10

NDC 12634-424-01 Bottles of 100

NDC 12634-424-09 Bottles of 35

NDC 12634-424-12 Bottles of 120

NDC 12634-424-18 Bottles of 180

NDC 12634-424-40 Bottles of 40

NDC 12634-424-42 Bottles of 42

NDC 12634-424-45 Bottles of 45

NDC 12634-424-50 Bottles of 50

NDC 12634-424-52 Blister Pack of 12

NDC 12634-424-54 Blister Pack of 14

NDC 12634-424-57 Blister Pack of 20

NDC 12634-424-59 Blister Pack of 30

NDC 12634-424-60 Bottles of 60

NDC 12634-424-61 Blister Pack of 10

NDC 12634-424-63 Blister Pack of 3

NDC 12634-424-66 Blister Pack of 6

NDC 12634-424-67 Blister Pack of 7

NDC 12634-424-69 Blister Pack of 9

NDC 12634-424-71 Bottles of 30

NDC 12634-424-74 Bottles of 24

NDC 12634-424-78 Bottles of 28

NDC 12634-424-79 Bottles of 25

NDC 12634-424-80 Bottles of 20

NDC 12634-424-81 Bottles of 21

NDC 12634-424-82 Bottles of 12

NDC 12634-424-84 Bottles of 14

NDC 12634-424-85 Bottles of 15

NDC 12634-424-90 Bottles of 90

NDC 12634-424-91 Blister Pack of 1

NDC 12634-424-92 Bottles of 2

NDC 12634-424-93 Bottles of 3

NDC 12634-424-94 Bottles of 4

NDC 12634-424-95 Bottles of 5

NDC 12634-424-96 Bottles of 6

NDC 12634-424-97 Bottles of 7

NDC 12634-424-98 Bottles of 8

NDC 12634-424-99 Bottles of 9

Store at 20º to 25ºC (68 to 77ºF) [See USP Controlled Room Temperature]. Dispense contents in a tight, light-resistant container as defined in the USP, with a child-resistant closure, as required.

Manufactured by:

Epic Pharma, LLC

Laurelton, NY 11413

Manufactured in USA

Revised January 2016

MF012REV01/16

OE1035

Repackaged & Distributed by:

Apotheca Inc.

Phoenix, AZ 85006

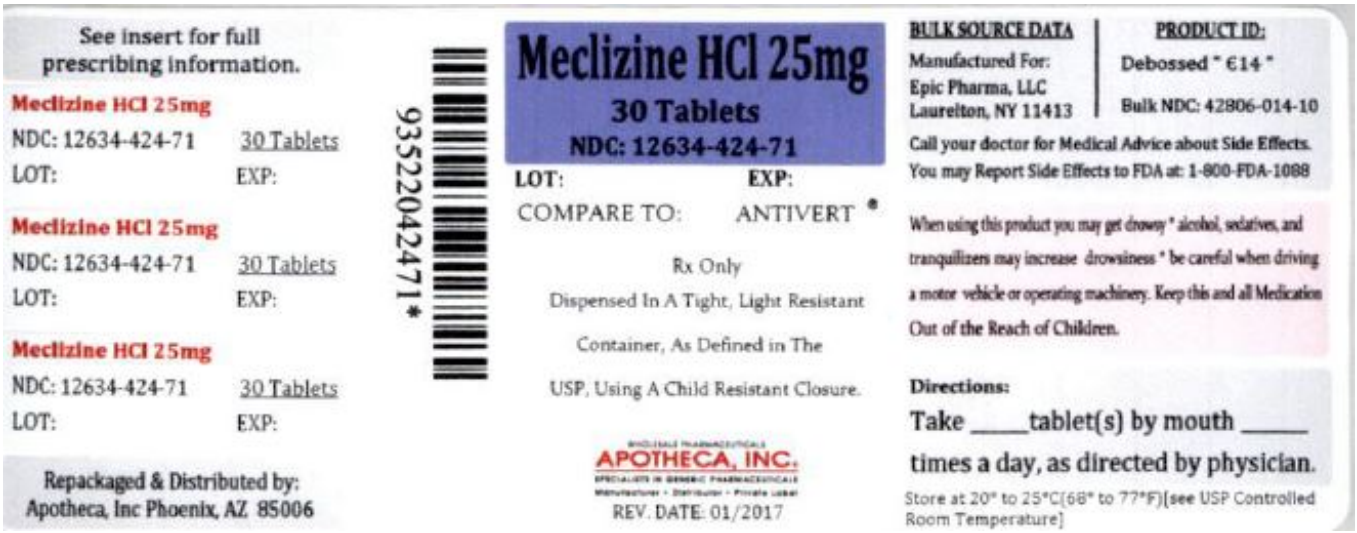
PRINCIPAL DISPLAY PANEL – 25 mg, 30 Tablets

Meclizine Hydrochloride Tablets USP, 25 mg

25 mg

Rx Only

30 Tablets



MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:12634-424(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:12634-424-00	10 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
2	NDC:12634-424-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
3	NDC:12634-424-09	35 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
4	NDC:12634-424-12	120 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
5	NDC:12634-424-18	180 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
6	NDC:12634-424-40	40 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
7	NDC:12634-424-42	42 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
8	NDC:12634-424-45	45 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
9	NDC:12634-424-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
10	NDC:12634-424-52	12 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/30/2012	
11	NDC:12634-424-54	14 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/30/2012	
12	NDC:12634-424-57	20 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/30/2012	
13	NDC:12634-424-59	30 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/30/2012	
14	NDC:12634-424-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
15	NDC:12634-424-61	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/30/2012	
16	NDC:12634-424-63	3 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/30/2012	
17	NDC:12634-424-66	6 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/30/2012	
18	NDC:12634-424-67	7 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/30/2012	
19	NDC:12634-424-69	9 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/30/2012	
20	NDC:12634-424-71	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
21	NDC:12634-424-74	24 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
22	NDC:12634-424-78	28 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
23	NDC:12634-424-79	25 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
24	NDC:12634-424-80	20 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
25	NDC:12634-424-81	21 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
26	NDC:12634-424-82	12 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
27	NDC:12634-424-84	14 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
28	NDC:12634-424-85	15 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
29	NDC:12634-424-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
30	NDC:12634-424-91	1 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/30/2012	
31	NDC:12634-424-92	2 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
32	NDC:12634-424-93	3 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
33	NDC:12634-424-94	4 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
34	NDC:12634-424-95	5 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
35	NDC:12634-424-96	6 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
36	NDC:12634-424-97	7 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	

37	NDC:12634-424-98	8 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	
38	NDC:12634-424-99	9 in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA200294	04/30/2012	

Labeler - Apotheca Inc. (051457844)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Inc.		051457844	relabel(12634-424) , repack(12634-424)

Revised: 1/2017 Apotheca Inc.