

MECLIZINE HYDROCHLORIDE- meclizine hydrochloride tablet
RedPharm Drug, Inc.

Meclizine 25mg tabs

1 INDICATIONS AND USAGE

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

2 DOSAGE AND ADMINISTRATION

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.

Chewable Tablets

Meclizine hydrochloride chewable tablets must be chewed or crushed completely before swallowing. Do not swallow chewable tablets whole.

3 DOSAGE FORMS AND STRENGTHS

Tablets

12.5 mg: oval-shaped, biconvex, two-layered tablet, one blue to pale blue layer debossed with "34" and one white to off white layer debossed with "L".

25 mg: oval-shaped, biconvex, two-layered tablet, one yellow to pale yellow layer debossed with "49" and one white to off white layer debossed with "L".

50 mg: oval-shaped, biconvex, two-layered tablet, one blue to pale blue layer debossed with "50" and one yellow to pale yellow layer and debossed with "L".

Chewable Tablets

25 mg: pink colored round tablets debossed with "M 25" on one side and break line on other side.

4 CONTRAINDICATIONS

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

5 WARNINGS AND PRECAUTIONS

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.

6 ADVERSE REACTIONS

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.

To report SUSPECTED ADVERSE REACTIONS, contact Rising Pharmaceuticals, Inc. at 1-866-562-4597 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

7 DRUG INTERACTIONS

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.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Data from epidemiological studies have not generally indicated a drug-associated risk of major birth defects with meclizine during pregnancy. However, in a published study, an increased incidence of fetal malformations was observed following oral administration of

meclizine to pregnant rats during the period of organogenesis, at doses similar to those used clinically.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. The background risk of major birth defects and miscarriage for the indicated population is unknown.

Data

Human Data

Epidemiological studies reporting on pregnancies exposed to meclizine have not identified an association between the use of meclizine during pregnancy and an increased risk of major birth defects.

Animal Data

In a published study, oral administration of meclizine (25-250 mg/kg) to pregnant rats during the period of organogenesis resulted in a high incidence of fetal malformations. These effects occurred at doses as low as 25 mg/kg, which is approximately 2 times the maximum recommended human dose (100 mg) on a body surface area (mg/m²) basis.

8.2 Lactation

Risk Summary

There are no data on the presence of meclizine in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for meclizine hydrochloride and any potential adverse effects on the breastfed infant from meclizine hydrochloride or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

8.6 Hepatic Impairment

The effect of hepatic impairment on the pharmacokinetics of meclizine has not been evaluated. As meclizine hydrochloride undergoes metabolism, hepatic impairment may result in increased systemic exposure of meclizine. Treatment with meclizine hydrochloride should be administered with caution in patients with hepatic impairment.

8.7 Renal Impairment

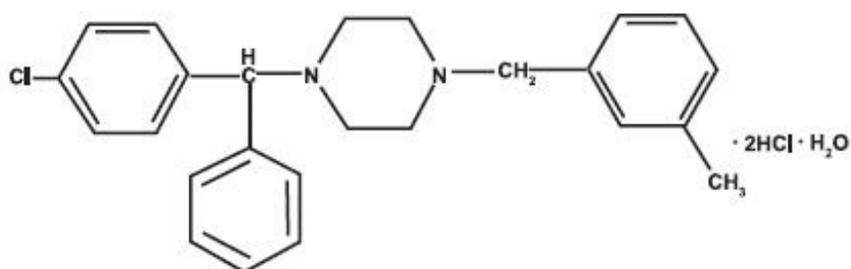
The effect of renal impairment on the pharmacokinetics of meclizine has not been evaluated. Because of a potential for drug/metabolite accumulation, meclizine hydrochloride should be administered with caution in patients with renal impairment and in the elderly, as renal function generally declines with age.

8.8 Genetic CYP2D6 Polymorphism

The genetic polymorphism of CYP2D6 that results in poor-, intermediate-, extensive-, and ultrarapid metabolizer phenotypes could contribute to large inter-individual variability in meclizine exposure. Therefore, when meclizine hydrochloride is administered to patients with CYP2D6 polymorphism, monitor for adverse reactions and clinical effect accordingly.

11 DESCRIPTION

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



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

Tablets

Inactive ingredients for the tablets are: corn starch; dibasic calcium phosphate; magnesium stearate; polyethylene glycol; sucrose. The 12.5 mg tablets also contain: FD&C Blue # 1. The 25 mg tablets also contain: FD&C Yellow # 6 and D&C Yellow # 10. The 50 mg tablets also contain: FD&C Blue # 1, FD&C Yellow # 6 and D&C Yellow # 10.

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.

Chewable Tablets

Inactive ingredients for the chewable tablets are: corn starch, colloidal silicon dioxide, FD&C Red # 40, lactose monohydrate, magnesium stearate, raspberry flavor, saccharin sodium, and talc.

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

12 CLINICAL PHARMACOLOGY

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 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.

Elimination

Meclizine has a plasma elimination half-life of about 5-6 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 NONCLINICAL TOXICOLOGY

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 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Tablets

Meclizine hydrochloride **12.5 mg** tablets are oval shaped, biconvex, two-layered tablet, one blue to pale blue layer debossed with “34” and one white to off white layer debossed with “L”.

Bottles of 100 NDC 16571-660-01

Bottles of 500 NDC 16571-660-50

Meclizine hydrochloride **25 mg** tablets are oval shaped, biconvex, two-layered tablet, one yellow to pale yellow layer debossed with “49” and one white to off white layer debossed with “L”.

Bottles of 100 NDC 16571-661-01

Bottles of 1000 NDC 16571-661-10

Meclizine hydrochloride **50 mg** tablets are oval shaped, biconvex, two-layered tablet, one blue to pale blue layer debossed with “50” and one yellow to pale yellow layer and debossed with “L”.

Bottles of 100 NDC 16571-662-01

Chewable Tablets

Meclizine hydrochloride **25 mg** chewable tablets are pink colored round tablets debossed with “M 25” on one side and break line on other side.

Bottles of 100 NDC 16571-663-01

16.2 Storage and Handling

Store at 20 °C to 25 °C (68 °F to 77 °F) [See USP Controlled Room Temperature]. Dispense in a tight, light-resistant container (USP).

17 PATIENT COUNSELING INFORMATION

Administration Instructions

Advise patients that the tablets must be swallowed whole, but chewable tablets must be chewed or crushed completely before swallowing [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)*].

PIA66201-00

Distributed by:

Rising Pharmaceuticals, Inc.
Saddle Brook, NJ 07663

Issued: 08/2019

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

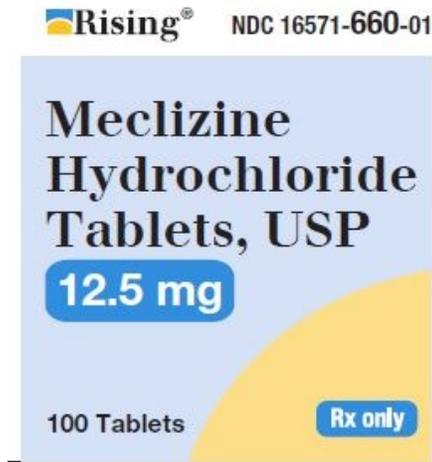
NDC 16571-660-01

Meclizine Hydrochloride Tablets, USP

12.5mg

Rx Only

Container Label



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

USUAL DOSAGE:
See accompanying prescribing Information.

VERTIGO:
25 mg to 100 mg in divided doses daily
depending on the clinical response.

Dispense in tight, light – resistant containers
(USP).

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

Store at 20° to 25°C (68° to 77°F). [See
USP Controlled Room Temperature].

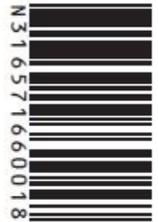
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Made in India

Code: TS/DRUGS/22/2009

LA66001-00

Issued: 08/2019



P1424296

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NDC 16571-661-01

Meclizine Hydrochloride Tablets, USP

25mg

Rx Only

Container Label



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

USUAL DOSAGE:
See accompanying prescribing Information.

VERTIGO:
25 mg to 100 mg in divided doses daily
depending on the clinical response.

Dispense in tight, light – resistant containers
(USP).

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

Store at 20° to 25°C (68° to 77°F). [See
USP Controlled Room Temperature].

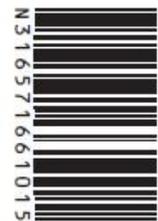
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Made in India

Code: TS/DRUGS/22/2009

LA66101-00

Issued: 08/2019

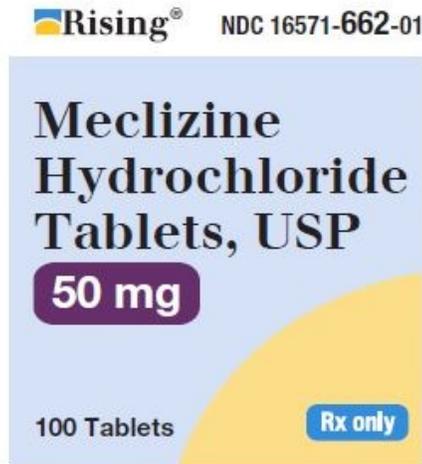


P1424297

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NDC 16571-662-01

Meclizine Hydrochloride Tablets, USP
50mg
Rx Only
Container Label



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

USUAL DOSAGE:
See accompanying prescribing Information.

VERTIGO:
25 mg to 100 mg in divided doses daily
depending on the clinical response.

Dispense in tight, light – resistant containers
(USP).

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

Store at 20° to 25°C (68° to 77°F). [See
USP Controlled Room Temperature].

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Made in India

Code: TS/DRUGS/22/2009

LA66201-00

Issued: 08/2019



P 1424299



NDC 16571-663-01

Meclizine Hydrochloride Chewable Tablets, USP
25mg
Rx Only
Container Label



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

**Chew or crush tablets completely before
swallowing.**

Do not swallow tablets whole.

USUAL DOSAGE:
See accompanying prescribing Information.

VERTIGO:
25 mg to 100 mg in divided doses daily
depending on the clinical response.

Dispense in tight, light – resistant containers
(USP).

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

Store at 20° to 25°C (68° to 77°F). [See USP
Controlled Room Temperature].

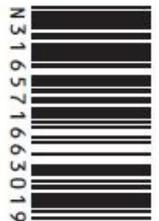
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Saddle Brook, NJ 07663

Made in India

Code: TS/DRUGS/22/2009

LA66301-00

Issued: 08/2019



P 1424469



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



NDC: 67296-1432-3
MECLIZINE HCL
 25MG
 30 Tablets

Rx Only

Lot: 20015AX1

Exp: 10/22

(01)00367296143232
 (21)100000000000038
 (17)221031
 (10)20015AX1

Usual adult dosage: See package insert
 Store at controlled room temperature: 20-25 C (68-77 F)

Mfg: Rising Pharmaceuticals Inc
 Saddle Brook NJ 07663
 16571-661-10

Dist. by: Redpharm Drug Eden Prairie, MN 55344

SIN 25210



MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:67296-1432(NDC:16571-661)
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
STARCH, CORN (UNII: O8232NY3SJ)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0K00R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics

Color	yellow (Pale Yellow to White)	Score	no score
Shape	OVAL (Biconvex, two layered tablet)	Size	13mm
Flavor		Imprint Code	49;L
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67296-1432-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2021	
2	NDC:67296-1432-7	21 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA010721	01/15/2020	

Labeler - RedPharm Drug, Inc. (828374897)

Establishment

Name	Address	ID/FEI	Business Operations
EPM Packaging, Inc.		079124340	repack(67296-1432)

Revised: 2/2023

RedPharm Drug, Inc.