

MECLIZINE HYDROCHLORIDE- meclizine hydrochloride tablet, film coated

Chartwell RX, LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use MECLIZINE HYDROCHLORIDE TABLETS safely and effectively. See full prescribing information for MECLIZINE HYDROCHLORIDE TABLETS.

MECLIZINE hydrochloride tablets, for oral use
Initial U.S. Approval: 1957

INDICATIONS AND USAGE

Meclizine hydrochloride tablet is indicated for the treatment of vertigo associated with diseases affecting the vestibular system in adults (1).

DOSAGE AND ADMINISTRATION

- Recommended dosage: 25 mg to 100 mg daily, in divided doses (2.1).
- Tablets: Swallow whole (2.2).

DOSAGE FORMS AND STRENGTHS

- Tablets: 12.5 mg, 25 mg, and 50 mg (3).

CONTRAINDICATIONS

Meclizine hydrochloride tablets are contraindicated in patients with hypersensitivity to meclizine or any of the inactive ingredients (4).

WARNINGS AND PRECAUTIONS

- May cause drowsiness: Use caution when driving a car or operating dangerous machinery (5.1).
- Potential anticholinergic action: this drug should be prescribed with care to patients with a history of asthma, glaucoma, or enlargement of the prostate gland (5.2).

ADVERSE REACTIONS

Common adverse reactions are anaphylactic reaction, drowsiness, dry mouth, headache, fatigue, and vomiting. On rare occasions blurred vision has been reported (6).

To report SUSPECTED ADVERSE REACTIONS, contact Chartwell RX, LLC at 1-845-232-1683, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Coadministration of meclizine hydrochloride tablets with other CNS depressants, including alcohol, may result in increased CNS depression (7.1).
- CYP2D6 inhibitors: As meclizine is metabolized by CYP2D6, there is a potential for drug-drug interactions between meclizine hydrochloride tablets and CYP2D6 inhibitors (7.2).

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 3/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

2.2 Administration Instructions

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

5.1 Drowsiness

5.2 Concurrent Medical Conditions

6 ADVERSE REACTIONS

7 DRUG INTERACTIONS

7.1 CNS Depressants

7.2 CYP2D6 Inhibitors

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

8.2 Lactation

8.4 Pediatric Use

8.5 Geriatric Use

8.6 Hepatic Impairment

8.7 Renal Impairment

8.8 Genetic CYP2D6 Polymorphism

11 DESCRIPTION

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

12.2 Pharmacodynamics

12.3 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

16.2 Storage and Handling

17 PATIENT COUNSELING INFORMATION

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Meclizine hydrochloride tablet 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.

3 DOSAGE FORMS AND STRENGTHS

Tablets

- 12.5 mg: White to off-white, oval shaped, film-coated tablets, debossed with “ **CE**” on one side and “ **256**” on the other side.
- 25 mg: White to off-white, oval shaped, film-coated tablets, debossed with “ **CE**” on one side and “ **257**” on the other side.
- 50 mg: White to off-white, oval shaped, film-coated scored tablets, debossed with “ **C**” breakline “ **E**” on one side and “ **258**” on the other side.

4 CONTRAINDICATIONS

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 WARNINGS AND PRECAUTIONS

5.1 Drowsiness

Since drowsiness may occur with use of meclizine hydrochloride tablets, 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 tablets [see *DRUG INTERACTIONS* (7.1)].

5.2 Concurrent Medical Conditions

Because of its potential anticholinergic action, meclizine hydrochloride tablets 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 tablets 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 DRUG INTERACTIONS

7.1 CNS Depressants

There may be increased CNS depression when meclizine hydrochloride tablets are 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 tablets 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 to 4% and 15 to 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 to 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 tablets undergoes metabolism, hepatic impairment may result in increased systemic exposure of meclizine. Treatment with meclizine hydrochloride tablets should be administered with caution in patients with hepatic impairment.

8.7 Renal Impairment

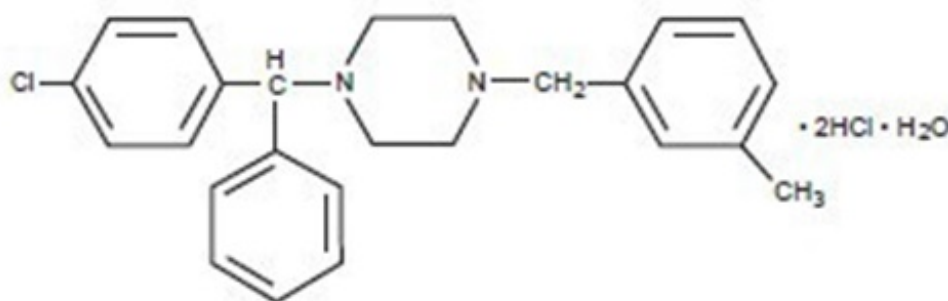
The effect of renal impairment on the pharmacokinetics of meclizine has not been evaluated. Because of a potential for drug/metabolite accumulation, meclizine hydrochloride tablets should be administered with caution in patients with renal impairment and in the elderly, as renal function generally declines 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 tablets are administered to patients with CYP2D6 polymorphism, monitor for adverse reactions and clinical effect accordingly.

11 DESCRIPTION

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



Molecular Weight - 481.88

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

Tablets

Inactive ingredients for the tablets are: colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, sodium starch glycolate, stearic acid, talc and titanium dioxide.

Meclizine hydrochloride tablets, USP are available in three strengths, 12.5 mg, 25 mg and 50 mg.

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

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

Each meclizine hydrochloride, USP 50 mg tablet contains 50 mg of meclizine dihydrochloride equivalent to 42.14 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 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 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 Tablets, USP, **12.5 mg** are white to off-white, oval shaped, film-coated tablets, debossed with “**CE**” on one side and “**256**” on the other side.

They are supplied as follows:

Bottle of 90 NDC # 62135-952-90

Meclizine Hydrochloride Tablets, USP, **25 mg** are white to off-white, oval shaped, film-coated tablets, debossed with “**CE**” on one side and “**257**” on the other side.

They are supplied as follows:

Bottle of 90 NDC # 62135-953-90

Meclizine Hydrochloride Tablets, USP, **50 mg** are white to off-white, oval shaped, film-coated scored tablets, debossed with “**C**” breakline “**E**” on one side and “**258**” on the other side.

They are supplied as follows:

Bottle of 60 NDC # 62135-954-60

16.2 Storage and Handling

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, as defined in the USP with a child-resistant closure, as required.

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 tablets 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 tablets 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 tablets 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)**].


Manufactured for:
Chartwell RX, LLC.
Congers, NY 10920

L72582

Rev. 03/2025-01

PRINCIPAL DISPLAY PANEL

Meclizine Hydrochloride Tablets, USP 12.5 mg - NDC 62135-952-90 - 90s Tabs Bottle Label

<p>NDC 62135-952-90</p> <p>Meclizine Hydrochloride Tablets, USP</p> <p>12.5 mg</p> <p>Rx Only 90 Tablets</p> <p>Chartwell Rx</p>	<p>Each film-coated tablet contains 12.5 mg meclizine hydrochloride, USP.</p> <p>Storage: 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].</p> <p>Dispense in a tight, light-resistant container, as defined in the USP with a child-resistant closure, as required.</p> <p>DOSAGE AND USE: See accompanying prescribing information. VERTIGO: 25 mg to 100 mg in divided doses daily depending on the clinical response.</p> <p>KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.</p> <p>Manufactured For: Chartwell RX, LLC. Congers, NY 10920</p> <p>GTIN 00362135952907 L72579 REV.01 02/25</p> <p> N 3 62135 95290 7</p>	<p>No Varnish</p>
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Meclizine Hydrochloride Tablets, USP 25 mg - NDC 62135-953-90 - 90s Tabs Bottle Label

NDC 62135-953-90

Mecizine

Hydrochloride

Tablets, USP

25 mg

Rx Only
90 Tablets

Chartwell Rx

Each film-coated tablet contains 25 mg mecizine hydrochloride, USP.

Storage: 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, as defined in the USP with a child-resistant closure, as required.

DOSAGE AND USE: See accompanying prescribing information. VERTIGO: 25 mg to 100 mg in divided doses daily depending on the clinical response.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured For: Chartwell RX, LLC.
Congers, NY 10920

GTIN 00362135953904 L72580 REV. 01/02/25

N 3

6213595390

4

No Varnish

Mecizine Hydrochloride Tablets, USP 50 mg - NDC 62135-954-60 - 60s Tabs Bottle Label

NDC 62135-954-60

Mecizine

Hydrochloride

Tablets, USP

50 mg

Rx Only
60 Tablets

Chartwell Rx

Each film-coated tablet contains 50 mg mecizine hydrochloride, USP.

Storage: 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, as defined in the USP with a child-resistant closure, as required.

DOSAGE AND USE: See accompanying prescribing information. VERTIGO: 25 mg to 100 mg in divided doses daily depending on the clinical response.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured For: Chartwell RX, LLC.
Congers, NY 10920

GTIN 00362135954604 L72581 REV. 01/02/25

N 3

6213595460

4

No Varnish

MECLIZINE HYDROCHLORIDE			
mecizine hydrochloride tablet, film coated			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62135-952
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE -		MECLIZINE	12.5 mg

UNII:3L5TQ84570)		HYDROCHLORIDE		12.5 mg
Inactive Ingredients				
Ingredient Name				Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STARCH, CORN (UNII: O8232NY3SJ)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	white (white to off-white)		Score	no score
Shape	OVAL		Size	11mm
Flavor			Imprint Code	CE;256
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62135-952-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/04/2025	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA203003		08/11/2022	

MECLIZINE HYDROCHLORIDE			
meclizine hydrochloride tablet, film coated			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62135-953
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)	
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (white to off-white)	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	CE;257
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62135-953-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/04/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203003	08/11/2022	

MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:62135-954
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)		MECLIZINE HYDROCHLORIDE	50 mg	
Inactive Ingredients				
Ingredient Name			Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STARCH, CORN (UNII: O8232NY3SJ)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	white (white to off-white)	Score	2 pieces	
Shape	OVAL	Size	16mm	
Flavor		Imprint Code	C;E;258	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62135-954-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/04/2025	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA203003		08/11/2022	

Labeler - Chartwell RX, LLC (079394054)

Establishment

Name	Address	ID/FEI	Business Operations
Chartwell Pharmaceuticals Congers, LLC		118673447	manufacture(62135-952, 62135-953, 62135-954)