NAUS-EASE- meclizine hydrochloride tablet
Sunascen Therapeutics LLC

NAUS-EASE® (Meclizine Hydrochloride), USP; Tablet - Product Information

ACTIVE INGREDIENTS

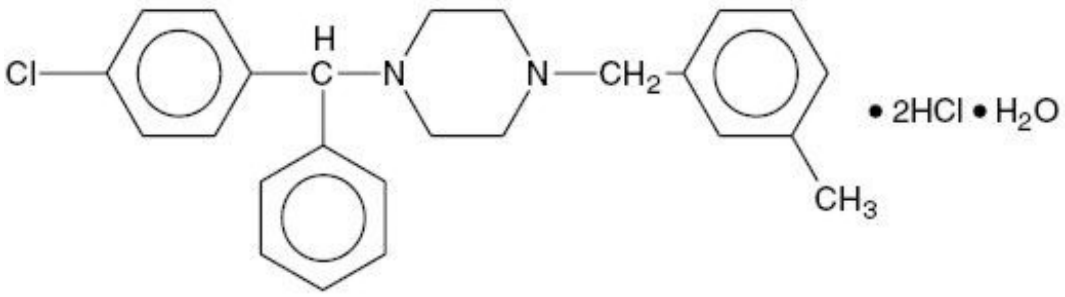
Meclizine Hydrochloride, USP 25 mg

PURPOSE

Antiemetic

DESCRIPTION

Chemically, Meclizine Hydrochloride, USP is 1-(*p*-Chloro-α-phenylbenzyl)-4-(*m*-methylbenzyl) piperazine dihydrochloride monohydrate. Meclizine Hydrochloride, USP is an oral antiemetic, which is a white to slightly yellowish crystalline powder having a slight odor and is tasteless. The molecular weight is 481.89 g/mol. It has the following structural formula:



$C_{25}H_{27}ClN_2 \cdot 2HCl \cdot H_20$ M.W. 481.88544 g/mol

CLINICAL PHARMACOLOGY

Meclizine Hydrochloride, USP 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 Hydrochloride, USP following oral administration has been summarized from published literature.

Absorption

Meclizine Hydrochloride, USP 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 Hydrochloride, USP in humans remains unknown.

Metabolism

The metabolic fate of Meclizine Hydrochloride, USP 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 Hydrochloride, USP.

The genetic polymorphism of CYP2D6 that results in extensive-, poor-, intermediate- and ultrarapid metabolizer phenotypes could contribute to large inter-individual variability in Meclizine Hydrochloride, USP exposure.

Elimination

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

INDICATIONS AND USAGE

For Consumers (the general public):
Naus-Ease® (Meclizine Hydrochloride), USP Tablets are used for the prevention and treatment of nausea and vomiting, or dizziness associated with motion sickness.

For Health Professionals:
Based on a review of Meclizine Hydrochloride, USP drug by the National Academy of Sciences – National Research Council and/or other information, FDA has classified the indications of Meclizine Hydrochloride, USP as follows:
1. The prevention and treatment (management) of nausea and vomiting, and dizziness associated with motion sickness.
2. For the treatment of vertigo.

CONTRAINDICATIONS

Meclizine Hydrochloride, USP is contraindicated in individuals who have shown a previous hypersensitivity to it.

WARNINGS

Clinical studies establishing safety and effectiveness in children under 12 years of age have not been done; therefore, usage is not recommended in children under 12 years of age unless directed by a doctor.

Due to its potential anticholinergic action, do not take unless directed by a doctor if you

have a breathing problem such as asthma, emphysema, or chronic bronchitis, glaucoma, or difficulty in urination due to enlargement of the prostate gland.

Ask a doctor before use if you are taking sedatives or tranquilizers.

When using this product:
1. Do not exceed the recommended dosage.
2. May cause drowsiness.
3. Patients should avoid alcoholic beverages while taking this drug.
4. 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. Therefore patients are reminded caution when driving or operating machinery.
5. Alcohol, sedatives and tranquilizers may increase drowsiness.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, seek medical help or contact a Poison Control Center right away.
Call Poison Control at 1-800-222-1222

PRECAUTIONS

Pediatric Use

Clinical studies establishing safety and effectiveness in children under 12 years of age have not been done; therefore, usage is not recommended in children under 12 years of age unless directed by a doctor.

Pregnancy Use

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 Hydrochloride, USP 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 Hydrochloride, USP or any other medication, should be used during pregnancy only if clearly necessary, and after speaking with a health professional.

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 Hydrochloride, USP is administered to a nursing woman.

Hepatic Impairment

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

Renal Impairment

The effect of renal impairment on the pharmacokinetics of Meclizine Hydrochloride, USP has not been evaluated. Due to a potential for drug/metabolite accumulation, Meclizine Hydrochloride, USP 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 Hydrochloride, USP is administered concurrently with other CNS depressants, including alcohol, tranquilizers and sedatives. (see WARNINGS)

Based on in vitro evaluation, Meclizine Hydrochloride, USP is metabolized by CYP2D6. Therefore there is a possibility for a drug interaction between Meclizine Hydrochloride, USP and CYP2D6 inhibitors.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. In case of an overdose, seek medical help or contact a Poison Control Center immediately.
Call Poison Control at 1-800-222-1222.

ADVERSE REACTIONS

Anaphylactoid reaction, drowsiness, dry mouth, headache, fatigue, vomiting and, on rare occasions, blurred vision have been reported.

DOSAGE AND ADMINISTRATION (DIRECTIONS)

Adults and children 12 years of age and over: Take 1 to 2 Naus-Ease® (Meclizine Hydrochloride), USP Tablets (25 mg to 50 mg) by mouth once daily, or as directed by a physician.

The initial dose of 25 mg to 50 mg of Naus-Ease® (Meclizine Hydrochloride), USP Tablets should be taken one hour prior to travel for the prevention and treatment of motion sickness. Thereafter, the dose may be repeated every 24 hours for the duration of the journey.

INACTIVE INGREDIENTS

Each tablet contains the following inactive ingredients: Colloidal Silicon Dioxide, Croscarmellose Sodium, Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose, D&C Yellow #10, Aluminum Lake (15-20%).

OTHER USEFUL INFORMATION

Store at controlled room temperature 20-25°C (68-77°F).

Protect from heat and humidity.

Use by expiration date on package.

HOW SUPPLIED

Naus-Ease® (Meclizine Hydrochloride), USP Tablets are available in 25mg strengths, and is available in 8 and 16 count package sizes.

25 mg tablets; Yellow; Oval shaped; Scored; "TL121" imprinted on each tablet

Naus-Ease® (Meclizine Hydrochloride), USP; 8 Tablets: NDC 49467-124-08
Naus-Ease® (Meclizine Hydrochloride), USP; 16 Tablets: NDC 49467-124-16

Distributed by:
Sunascen Therapeutics LLC
Rockville, MD 20850 USA

QUESTIONS OR COMMENTS?

Sunascen Therapeutics LLC
PO Box 2773
Wilmington DE 19805

More information is available on the web at www.nausease.com

PRINCIPAL DISPLAY PANEL

Naus-Ease® (Meclizine Hydrochloride), USP; Tablets 25 mg Each
Antiemetic – Prevent and Treat: Nausea and Vomiting

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

NAUS~EASE®

PREVENT AND TREAT: NAUSEA & VOMITING

NDC 49467 - 124 - 08

NAUS~EASE®

MECLIZINE HYDROCHLORIDE - ANTIEMETIC

PREVENT AND TREAT:

NAUSEA & VOMITING

UP TO 24 HOURS OF RELIEF FROM A SINGLE DOSE

8 TABLETS (25 MG EACH)

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

Sunascen THERAPEUTICS

QUALITY GUARANTEED

3 49467 12408 0

Lot Number
Expiration Date

Distributed by: Sunascen Therapeutics LLC
Rockville, MD 20850 USA

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredients (in each tablet) — **Purpose**
Meclizine Hydrochloride, USP 25 mg ..... Antiemetic

Uses
For the prevention and treatment of nausea, vomiting, and dizziness associated with motion sickness.

Warnings
Do not take unless directed by a doctor if you have a breathing problem such as emphysema or chronic bronchitis, glaucoma, difficulty urinating due to an enlarged prostate gland.

Not for use in children under 12 years of age unless directed by a doctor.

Ask a doctor or a pharmacist before use if you are taking sedatives or tranquilizers.

When using this product
- Do not exceed the recommended dosage
- May cause drowsiness
- Avoid alcoholic beverages while taking this product
- Alcohol, sedatives, and tranquilizers may increase drowsiness
- Use caution when driving or operating machinery

Drug Facts (Continued)

Warnings (Continued)
If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, seek medical help or contact a Poison Control Center right away.
Call Poison Control at 1-800-222-1222

Directions
Adults and children 12 years of age and over: Take 1 to 2 tablets (25 mg to 50 mg) by mouth once daily, or as directed by a physician. To prevent and treat motion sickness, take within 1 hour prior to travel.

Other information
- Store at controlled room temperature 20° - 25° C (68° - 77° F)
- Protect from heat and humidity

Inactive ingredients
Colloidal Silicon Dioxide, Croscarmellose Sodium, Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose, D&C Yellow #10, Aluminum Lake.

Questions or Comments? PO Box 2773 Wilmington DE 19805
You can also visit us on the web at www.nausease.com

NAUS-EASE

meclizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49467-124
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Product Characteristics

Color	yellow	**Score**	2 pieces
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	TL121
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49467-124-08	1 in 1 CARTON	04/16/2012	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:49467-124-16	2 in 1 CARTON	04/16/2012	
2		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA	ANDA040659	04/16/2012	

Labeler - Sunascen Therapeutics LLC (078272834)

Registrant - Sunascen Therapeutics LLC (078272834)

Establishment

Name	Address	ID/FEI	Business Operations
Sunascen Therapeutics LLC		078272834	label(49467-124)

Revised: 1/2023 Sunascen Therapeutics LLC