NAUS-EASE - meclizine hydrochloride film, soluble
Sunascen Therapeutics LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

NAUS-EASE - Film; Product Information

Active Ingredients
Meclizine HCl 25 mg

Meclizine Hydrochloride is an oral antiemetic. It is a white to slightly yellow crystalline powder which has a slight odor and is tasteless. Meclizine HCl has the following structural formula:

C25H27CIN2 - 2HCI - H2O M.W. 481.89

The chemical name is 1-(p-chloro-alpha-phenylbenzyl)-4-(m-methyl-benzyl) - piperazine dihydrochloride monohydrate.

Purpose
Antiemetic

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 right away. Call Poison Control at 1-800-222-1222.

Indications and Use
For the prevention and treatment of nausea and vomiting, or dizziness associated with motion sickness

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

- Do not take unless directed by a doctor if you have a breathing problem such as 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. Avoid alcoholic beverages while taking this product
4. Alcohol, sedatives and tranquilizers may increase drowsiness
5. Use caution when driving or operating machinery

- 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: Oral dosage is 1 to 2 film strips (25 to 50mg) once daily, or as directed by a physician. Place 1 to 2 film strips on the tongue to completely dissolve then swallow.

Inactive Ingredients

- polyethylene oxide
- hydroxypropyl methylcellulose
- maltitol
- acesulfame potassium
- citric acid
- sodium citrate

Principal Display Panel

Meclizine HCl Film Strips, 25 mg Each
Antiemetic – Prevent and Treat: Nausea and Vomiting

Distributed by: Sunascen Therapeutics LLC
Rockville, MD 20850 USA

TAMPER EVIDENT: EACH FILM STRIP IS INDIVIDUALLY SEALED IN A POUCH. DO NOT USE IF INDIVIDUAL POUCH IS TORN, BROKEN, OR SHOWS ANY SIGNS OF TAMPERING.

Note:
Store at controlled room temperature 20-30°C. (68-86°F)
Protect from heat and humidity
Use by expiration date on package

NAUS-EASE 8 Film Strips: NDC 49467-104-01
NAUS-EASE 16 Film Strips: NDC 49467-104-16

Distributed by: Sunascen Therapeutics LLC
Rockville, MD 20850 USA
© Sunascen Therapeutics LLC 2012

Patent Pending

Sunascen THERAPEUTICS
QUALITY GUARANTEED

NAUS~EASE®

Meclizine Hydrochloride - Antiemetic

Prevent and Treat: Nausea & Vomiting

NDC 49467-104-01

8 Film Strips (25 mg EACH)

Lime Flavored

Lactose and Gluten Free

Lasts up to 24 hours

TAMPER EVIDENT: EACH FILM STRIP IS INDIVIDUALLY SEALED IN A POUCH. DO NOT USE IF INDIVIDUAL POUCH IS TORN, BROKEN, OR SHOWS ANY SIGNS OF TAMPERING.

No Print Area
Lot no. & Expiration Date

NAUS~EASE®
Prevent and Treat: Nausea & Vomiting

Drug Facts

Active Ingredient (In each film strip) — **Purpose**
(Meclizine HCl 25 mg) ..... Antiemetic

Uses
For the prevention and treatment of nausea and vomiting, or 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, or difficulty in urination due to enlargement of the prostate gland.

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

Ask a doctor 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

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

Drug Facts (Continued)

Directions
Adults and children 12 years of age and over: Oral dosage is 1 to 2 film strips (25 mg to 50 mg) once daily, or as directed by a physician. Place 1 to 2 film strips on the tongue. Allow each film strip to completely dissolve, then swallow.

Other Information
- Store at room temperature 20°-30° C (68°-86° F)
- Do not use if individual pouch is torn or broken
- See side panal for lot number and expiration date

Inactive Ingredients
Polyethylene oxide, hydroxypropyl methylcellulose, maltitol, acesulfame potassium, lime flavor, citric acid, sodium citrate, and FD&C green #3.

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

DOES NOT CONTAIN LACTOSE OR GLUTEN

3 49467 10401 3

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

GLUE LINE

GLUE LINE

GLUE LINE

NAUS-EASE

meclizine hydrochloride film, soluble

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49467-104
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
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MALTITOL (UNII: D65DG142WK)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ANHYDROUS TRISODIUM CITRATE (UNII: RS7A450LGA)	

Product Characteristics

Color	green	**Score**	no score
Shape	RECTANGLE	**Size**	22mm
Flavor	LIME	**Imprint Code**	S1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49467-104-01	8 in 1 CARTON		
1		1 in 1 POUCH		
2	NDC:49467-104-16	16 in 1 CARTON		
2		1 in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	04/16/2012	

Labeler - Sunascen Therapeutics LLC (078272834)