

RUGBY TRAVEL SICKNESS MECLIZINE HCL, 25 MG EACH (ANTIEMETIC)- meclizine hcl tablet, chewable

NuCare Pharmaceuticals, Inc.

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.

TRAVEL SICKNESS CHEWABLE TABLETS

Drug Facts

Active ingredient (in each chewable tablet)

Meclizine HCl USP 25 mg

Purpose

Antiemetic

Uses prevents and treats nausea, vomiting or dizziness due to motion sickness

Warnings

Do not use in children under 12 years of age unless directed by a doctor

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

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

When using this product

- may cause drowsiness
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- use caution when driving a motor vehicle or operating machinery

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

Keep out of reach of children. In case of overdose, get medical help or contact the poison control center immediately.

Directions

- Dosage should be taken one hour before travel starts
- **Adults and children 12 years of age and older:** Chew 1-2 tablets once daily, or as directed by a doctor
- **Children under 12 years:** do not give this product to children under 12 years of age unless directed by a doctor

Other information

- Phenylketonurics: Contains Phenylalanine 0.28 mg per tablet
- Store at room temperature in a dry place
- Keep lid tightly closed

Inactive ingredients

aspartame, croscarmellose sodium, dextrose, FD&C Red #40 Lake, magnesium stearate, maltodextrin, microcrystalline cellulose, natural and artificial flavors, silicon dioxide, sodium sulfate, sugar,

tricalcium phosphate.

Questions or comments?

call 1-800-645-2158

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Distributed by: Rugby Laboratories

17177 N. Laurel Park Drive, Suite 233, Livonia, MI 48152

NuCare Pharmaceuticals, Inc.

NDC 68071-4147-2
Lot #: 000000 Exp. Date: 00-00

Meclizine HCl 25mg #20 Chewtabs

Each chewtab contains:
Meclizine HCl, USP 25mg.....Antiemetic
Phenylethanamine 0.28 mg per tablet

Warnings: Ask a doctor before use if you have glaucoma, a breathing problem such as emphysema or chronic bronchitis, trouble urinating due to an enlarged prostate gland. Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers. When using this product may cause drowsiness, alcohol, sedatives and tranquilizers may increase drowsiness, avoid alcoholic drinks, use caution when driving a motor vehicle or operating machinery. If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact the poison control center immediately. Round Pink Scored Chewtab Debossed "21 G" on the scored side

Distributed by:
Rugby Laboratories Livonia, MI 48152
Packaged by:
NuCare Pharmaceuticals, Inc.
Orange, CA 92867

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Chew every 6 hours 4 times a day.

WARNING: KEEP OUT OF REACH OF CHILDREN. STORE AT CONTROLLED TEMPERATURE 59-86°F.

Product #: P1763020

RUGBY TRAVEL SICKNESS MECLIZINE HCL, 25 MG EACH (ANTIEMETIC)			
meclizine hcl tablet, chewable			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-4147(NDC:0536-1018)
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
ASPARTAME (UNII: Z0H242BBR1)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
DEXTROSE (UNII: IY9XDZ35W2)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			

MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
SUCROSE (UNII: C151H8M554)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	

Product Characteristics

Color	pink	Score	2 pieces
Shape	ROUND (Biconvex Uncoated Tablet with Bisect)	Size	8mm
Flavor		Imprint Code	21G
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-4147-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2017	
2	NDC:68071-4147-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2017	
3	NDC:68071-4147-4	40 in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2017	
4	NDC:68071-4147-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	08/19/2014	

Labeler - NuCare Pharmaceuticals, Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	repack(68071-4147)

Revised: 11/2017

NuCare Pharmaceuticals, Inc.