

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

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

Inactive ingredients

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

Questions or comments?

1-800-645-2158

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

See insert for full prescribing information.

Meclizine HCl 25mg
NDC: 12634-246-71 30 Chewable Tablets
LOT: EXP:

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Repackaged & Distributed by:
Apotheca, Inc Phoenix, AZ 85006

93522024671*

Meclizine HCl 25mg
30 Chewable Tablets
NDC: 12634-246-71
LOT: EXP:
COMPARE TO: ANTIVERT®

Rx Only
Dispensed In A Tight, Light Resistant Container, As Defined in The USP, Using A Child Resistant Closure.

WORLDWIDE PHARMACEUTICALS
APOTHECA, INC.
SPECIALISTS IN GENERIC PHARMACEUTICALS
Manufacturer • Distributor • Private Label
REV. DATE: 12/2015

BULK SOURCE DATA
Distributed By:
Rugby Laboratories
Livonia, MI 48150

PRODUCT ID:
Debossed * 21 | G *
Bulk NDC: 0536-1018-10

Call your doctor for Medical Advice about Side Effects.
You may Report Side Effects to FDA at: 1-800-FDA-1088

When using this product you may get drowsy * alcohol, sedatives, and tranquilizers may increase drowsiness * be careful when driving a motor vehicle or operating machinery. Keep this and all Medication Out of the Reach of Children. Other information: Phenylketonurics; each tablet contains: contains: phenylalanine 0.28 mg., Aspartame.

Directions:
Take ____ tablet(s) by mouth ____ times a day, as directed by physician.
Store at 20-25 C (68-77 F) [See USP Controlled Room Temperature] Protect from light and moisture.

RUGBY TRAVEL SICKNESS MECLIZINE HCL, 25 MG EACH (ANTIEMETIC)

meclizine hcl tablet, chewable

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:12634-246(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)	
MALTO DEXTRIN (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:12634-246-00	10 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:12634-246-01	100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:12634-246-71	30 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:12634-246-79	25 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:12634-246-80	20 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:12634-246-85	15 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:12634-246-91	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
8	NDC:12634-246-96	6 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

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

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Inc.		051457844	relabel(12634-246) , repack(12634-246)

Revised: 12/2015

Apotheca Inc.