MOTION SICKNESS RELIEF- meclizine hcl tablet, chewable PuraCap Pharmaceutical 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.

Motion Sickness Relief

Active ingredient (in each tablet)

Meclizine Hydrochloride 25 mg

Purpose

Antiemetic

Uses

for prevention and treatment of these symptoms associated with motion sickness:

- nausea
- vomiting
- dizziness

Warnings

Do not use

for children under 12 years of age unless directed by a doctor

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- 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

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

If pregnant or breast-feeding,

ask a doctor before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- take first dose one hour before starting activity
- adults and children 12 years and over: 1 to 2 tablets once daily, or as directed by a doctor

Other information

- Phenylketonurics: each tablet contains: phenylalanine 0.28 mg
- store at room temperature 15° 30°C (59° 86°F)

Inactive ingredients

Aspartame, compressible sugar, croscarmellose sodium, dextrose, FD&C red 40 (al-lake), magnesium stearate, microcrystalline cellulose, raspberry flavor

Questions or comments?

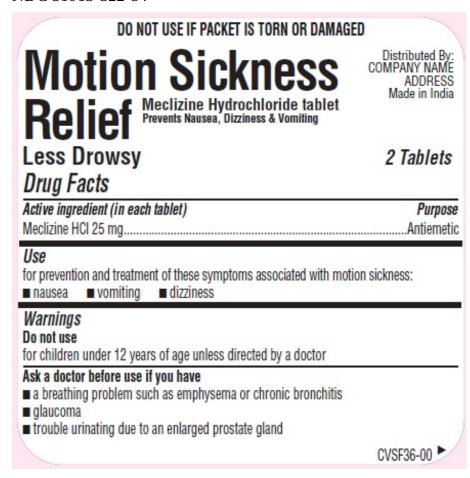
Call toll free: 1-855-215-8180

PRINCIPAL DISPLAY PANEL

Motion Sickness Relief

30 Tablets 15 Pouches (2 Tablets per Pouch)

NDC 51013-322-54



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Questions or comments?

Call toll free: 1-855-215-8180

Important: Read all product information before using. Keep the box for important information.

CVSB36-00

MOTION SICKNESS RELIEF

meclizine hcl tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51013-322
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

MECLIZINE HYDRO CHLO RIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570) | MECLIZINE HYDRO CHLO RIDE | 25 mg

Inactive Ingredients		
Ingredient Name	Strength	
ASPARTAME (UNII: Z0H242BBR1)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
DEXTRO SE (UNII: IY9 XDZ35W2)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
RASPBERRY (UNII: 4N14V5R27W)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
SUCROSE (UNII: C151H8 M554)		

Product Characteristics				
Color	red	Score	2 pieces	
Shape	ROUND	Size	8 mm	
Flavor	RASPBERRY	Imprint Code	AP;115	
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51013-322-54	15 in 1 CARTON	11/28/2017	
1		2 in 1 POUCH; 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	11/28/2017	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment				
Name	Address	ID/FEI	Business Operations	
Advance Pharmaceutical Inc.		078301063	manufacture(51013-322)	

Revised: 11/2017 PuraCap Pharmaceutical LLC