MOTION-TIME CHEWABLE- meclizine hcl tablet, chewable RedPharm Drug, 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.

MECLIZINE 25MG

Active ingredient (in each tablet)

Meclizine HCl 25 mg

Purpose

Antiemetic

Uses

prevents and treats nausea, vomiting, or dizziness associated with motion sickness

Warnings

Do not give to children under 12 years of age unless directed by a doctor

Do not take unless directed by a doctor if you have

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

Do not take if you are

taking sedatives or tranquilizers, without first consulting your doctor

When using this product

- do not exceed recommended dosage
- 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 health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- dosage should be taken one hour before travel starts
- adults and children 12 years of age and over: take 1 to 2 tablets once daily or as directed by a doctor

Other information

- store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F) in a dry place
- use by expiration date on package

Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, crospovidone, dextrose, FD-C red 40 aluminum lake, magnesium stearate, microcrystalline cellulose, modified corn starch, propylene glycol, raspberry flavor, silicon dioxide, sodium saccharin, stearic acid, talc, vanilla flavor

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



meclizine hcl tablet, chewable

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67296-1626(NDC:49483-333)	
Route of Administration	ORAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MECLIZINE HYDRO CHLO RIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	25 mg in 25

Inactive Ingredients			
Ingredient Name	Strength		
ANHYDRO US LACTO SE (UNII: 3S Y5LH9 PMK)			
CROSPOVIDONE (UNII: 68401960MK)			
DEXTROSE (UNII: IY9 XDZ35W2)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
RASPBERRY (UNII: 4N14V5R27W)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TALC (UNII: 7SEV7J4R1U)			
VANILLA (UNII: Q74T35078H)			

Product Characteristics			
Color	pink	Score	2 pieces
Shape	ROUND	Size	9 mm
Flavor	RASPBERRY	Imprint Code	TCL333
Contains			

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:67296-1626-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 1/20 19	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	0 1/0 1/20 19	

Labeler - RedPharm Drug, Inc. (828374897)

Establishment			
Name	Address	ID/FEI	Business Operations
RedPharm Drug, Inc.		828374897	repack(67296-1626), relabel(67296-1626)

Revised: 1/2019 RedPharm Drug, Inc.