

MOTION-TIME CHEWABLE- meclizine hcl tablet, chewable
Time-Cap Labs, 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.

4483-333 - MOTION TIME

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
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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
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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
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Other information

MOTION-TIME CHEWABLE

meclizine hcl tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-333
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 in 25

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CROSPVIDONE (UNII: 68401960MK)	
DEXTROSE (UNII: IY9XDZ35W2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
RASPBERRY (UNII: 4N14V5R27W)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
VANILLA (UNII: Q74T35078H)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-333-16	16 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/17/2018	
2	NDC:49483-333-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/17/2018	
3	NDC:49483-333-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/17/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	08/09/2010	

Labeler - Time-Cap Labs, Inc (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
Time-Cap Labs, Inc		037052099	manufacture(49483-333)

Revised: 12/2018

Time-Cap Labs, Inc