MECLIZINE- meclizine hcl 25mg tablet, chewable Ulai Health 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.

Drug Facts

Active ingredient (in each tablet)

Meclizine HCl 25mg

Purpose

Antiemetic

Uses

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

Warnings

Do not use

in children under 12 years of age unless directed by a doctor.

Do not take this product, unless directed by a doctor, if you have

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

Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor.

When using this product

- do not exceed recommended dosage
- may cause drowsiness
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- use causion 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 (1-800-222-1222).

Directions

• dosage should be taken one hour before travel starts

adults and children 12 years and over

take 1 or 2 tablets once daily or as directed by a doctor

Other information

• store at 20°-25°C (68°-77°F)

Inactive ingredients

croscarmellose sodium, dextrose, FD&C Red#40, raspberry flavor, magnesium stearate, microcrystalline cellulose, silicon dioxide, sodium saccharine, stearic acid

Questions or comments?

(866) 562-2756 (Mon-Fri 8 AM to 4 PM EST)

PHARBEST

NDC 73057-387-11

Manufactured in the USA

Chewable, Once-A-Day Protection

*Compare to the active ingredient in Bonine®

MECLIZINE

CHEWABLE

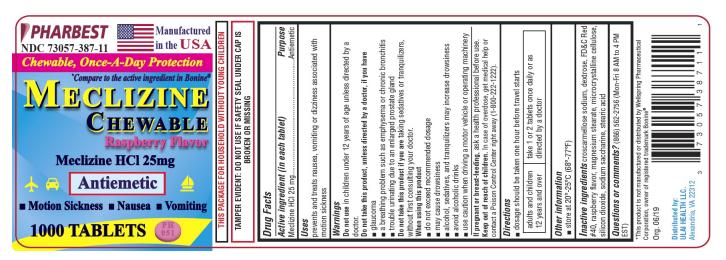
Raspberry Flavor

Meclizine HCl 25mg

Antiemetic

• Motion Sickness • Nausea • Vomiting

1000 TABLETS



MECLIZINE

meclizine hcl 25mg tablet, chewable

Product Information			
Product Type HUMAN OTC DRUG		Item Code (Source)	NDC:73057-387
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MECLIZINE HYDRO CHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TO84570)	MECLIZINE HYDROCHLORIDE	25 mg		

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)			
DEXTROSE (UNII: IY9 XDZ35W2)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
STEARIC ACID (UNII: 4ELV7Z65AP)			

Product Characteristics			
Color	pink (LIGHT PINK COLOR)	Score	2 pieces
Shape	ROUND (Round Tablet)	Size	8 mm
Flavor	RASPBERRY	Imprint Code	PH0 51
Contains			

l	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:73057-387-	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2019		
	2 NDC:73057-387- 08	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/08/2019		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	07/08/2019	

Labeler - Ulai Health LLC (081181535)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(73057-387), analysis(73057-387), pack(73057-387), label(73057-387)

Revised: 7/2019 Ulai Health LLC