MECLIZINE- meclizine hcl 25mg tablet, chewable Pharbest Pharmaceuticals, 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 tablet)

Meclizine HCI 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 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 a Poison Control Center right away (1-800-222-1222)

Directions

doage should be taken one hour before travel starts

Adults and children	take 1 or 2 tablets once daily
12 years and over	or as directed by doctor

Other information

- Tamper Evident: do not use if safety seal under cap is broken or missing
- 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, 8AM - 4PM EST)

PHARBEST

NDC 16103-387-11

Manufactured in the USA

Chewable, Once-A-Day Protection

*Compare to the active ingredient in Bonine®

MECLIZINE

CHEWABLE

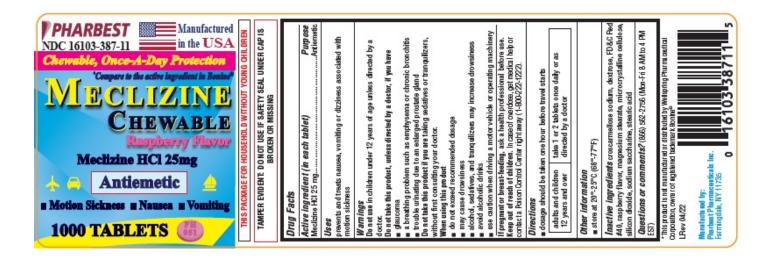
Raspberry Flavor

Meclizine HCI 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:16103-387
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII: 3L5TQ84570)	MECLIZ INE HYDROCHLORIDE	25 mg

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
DEXTROSE (UNII: IY9XDZ 35W2)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
RASPBERRY (UNII: 4N14V5R27W)			

Product Characteristics			
Color	pink (LIGHT PINK COLOR)	Score	2 pieces
Shape	ROUND (ROUND TABLET)	Size	8mm
Flavor		Imprint Code	PH051
Contains			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:16103- 387-08	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2018		
NDC:16103- 387-11	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2018		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	02/01/2018	

Labeler - Pharbest Pharmaceuticals, Inc. (557054835)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(16103-387) , pack(16103-387) , analysis(16103-387) , label(16103-387)

Revised: 4/2022 Pharbest Pharmaceuticals, Inc.