MECLIZINE- meclizine hcl 25mg 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 chew

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

Do not take unless directed by a doctor if you have

- glaucoma
- trouble urinating due to an enlarged prostate gland
- 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
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- 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

• doage should be taken 1 hour before travel starts

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

Other information

- **Tamper Evident:** do not use if safety seal under cap is broken or missing
- store at room temperature 20°-25°C (68°-77°F)

Inactive ingredients

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

Questions?

Adverse drug event call (800) 687-0176 (M - F, 8AM - 4PM EST).

NDC 66424-0387-01

*Compare to the active ingredient in Bonine ®

MECLIZINE

CHEWABLE

Raspberry Flavor

Meclizine HCl 25mg

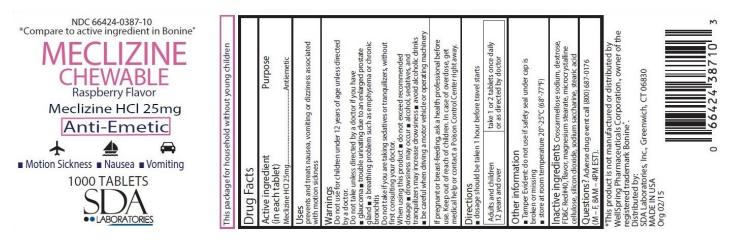
Anti-Emetic

• Motion Sickness • Nausea • Vomiting

100 TABLETS

SDA

LABORATORIES



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



Rx Only

NDC: 67296-1750-3 MECLIZINE HCL CHEWABLES

25MG

30 Tablets

Lot: 18F248X1

Exp: 06/20



Usual adult dosage: See package insert

Store at controlled room temperature: 20-25 C (68-77 F)

Mfg:

SDA Laboratories INC Greenwich CT 06830

66424-0387-10

Dist. by: Redpharm Drug Eden Prairie, MN 55344

SIN379206



MECLIZINE

meclizine hcl 25mg tablet, chewable

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:67296-1750(NDC:66424-387)

Route of Administration

ORAL

Active Ingredient/Active Moiety

STEARIC ACID (UNII: 4ELV7Z65AP)

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			
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 SO DIUM (UNII: SB8 ZUX40 TY)				

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

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:67296-1750-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 1/20 20			
Marketing Info	rmation				
Marketing Info		Marketing Start Date	Marketing End Date		
<u> </u>		Marketing Start Date 01/01/2020	Marketing End Date		

Labeler - RedPharm Drug, Inc. (828374897)

Establishment				
Name	Address	ID/FEI	Business Operations	
RedPharm Drug, Inc.		828374897	repack(67296-1750), relabel(67296-1750)	

Revised: 1/2020 RedPharm Drug, Inc.