# MECLIZINE HYDROCHLORIDE- meclizine hydrochloride 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.

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5172C- Rubgy

#### **Drug Facts**

Active ingredient (in each chewable tablet)

Meclizine HCl 25 mg

Purpose

**Antiemetic** 

#### Uses

prevents and treats nausea, vomiting or dizziness due to motion sickness

#### Do not use in

children under 12 years of age unless directed by a doctor

## Ask a doctor before use if you have

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□ a breathing problem such as emphysema or chronic bronchitis

trouble urinating due to an enlarged prostate gland

# Ask a doctor or pharmacist before use if

you are taking sedatives or tranquilizers

# When using this product

□ Do not exceed re	ecommended	dosage
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 $\hfill \square$  may cause drowsiness

 $\hfill \square$  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**

☐ Dosage should be taken one hour before travel starts

adults and children 12 years of age and over children under 12 years of age

chew 1 to 2 tablets once daily, or as directed by a doctor

do not give this product to children under 12 years of age unless directed by a doctor

#### Other information

☐ keep lid tightly closed

Croscarmellose Sodium, Crospovidone, FD&C Red #40 Lake, French Vanilla Flavor, Lactose, Magnesium Stearate, Raspberry Flavor, Silica, Sodium Saccharin, Stearic Acid

#### Questions or comments?

1-800-645-2158

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

\*This product is not manufactured or distributed by Wellspring Pharmaceutical Corporation, owner of the registered trademark Bonine®.

Distributed by: RUGBY® LABORATORIES Indianapolis, IN 46268 www.rugbylaboratories.com

Rugby

NDC 0536-1299-10 Compare to the active ingredient in Bonine\$\*

Meclizibe 25 mg

**Antiemetic** 

1000 Chewable Tablets



# Meclizine 25 mg

### **Antiemetic**

1000 Chewable Tablets

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Ask a dector before use if you have  glaucoma a a breathing problem such as emphyse trouble unnating due to an enlarged prostate gland	Ask a dector before use if you have B glaucoms B a breathing problem such as emphysema or chroric bronchrits B trouble urnating due to an enlarged prostate gland
Ask a doctor or pharmacist t	Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers
When using this product  Do not exceed recommende sedatives, and tranquilizers ma use caution when driving a r	When using this product  Be not exceed recommended dosage of rowsiness may occur of alcohol.  Sedatives, and tranquilizers may increase drowsiness of alcoholic drinks must exaction when driving a motor vehicle or operating machinesy.
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Directions = Dosage sho	Directions   Dosage should be taken one hour before travel starts
adults and children 12 years of age and over	chew 1 to 2 tablets once daily, or as directed by a doctor
children under 12 years of age	do not give to children under 12 years of age unless directed by a doctor
Other imormation   keep lid tightly closed	<b>Other information</b> ■ Store in a dry place at 15°-30°C (59°-36°F) ■ keep lid tightly closed
Inactive ingredients lake, french vanila flavor, lacto sodium saccharin, stearic acid.	Inactive ingredients croscamelloss sodium, crospovidone, FDKC red #40 latek, ferch vanilla flavor, lateks, magnesium stearale, raspberry flavor, silica, sodium saccherin, stearic acid.
Questions or comments?	mts? 1-800-645-2158
TAMPER IMPRINTED SAFETY SE	TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING
<sup>a</sup> This product is not manufactured or distributed by Wellspring Pharmaceutical Corporation, owner of the registered trademark Bonine <sup>®</sup> .	ctured or distributed Rev. 03/22 R-29 al Corporation, Re-order No. 371033 emark Bonine®, R50944

Lot # & Exp. Date:

# **MECLIZINE HYDROCHLORIDE**

meclizine hydrochloride tablet, chewable

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67296-1490(NDC:0536-1299)
Route of Administration	ORAL		

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

Inactive Ingredients				
Ingredient Name	Strength			
CROSPOVIDONE (UNII: 2S7830E561)				
VANILLA (UNII: Q74T35078H)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
RASPBERRY (UNII: 4N14V5R27W)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)				

Product Characteristics					
Color	pink (Rosy)	Score	2 pieces		
Shape	ROUND	Size	9mm		
Flavor	VANILLA, RASPBERRY	Imprint Code	5172		
Contains					

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67296- 1490-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/09/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	M009	10/30/2020		

# **Labeler -** Redpharm Drug, Inc. (828374897)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Redpharm Drug, Inc.		828374897	repack(67296-1490)		

Revised: 2/2023 Redpharm Drug, Inc.