# RUGBY TRAVEL SICKNESS- rugby travel sickness 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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#### SPL UNCLASSIFIED SECTION

**Drug Facts** 

#### ACTIVE INGREDIENT

Active ingredient (in each chewable tablet)

Meclizine HCl USP 25 mg

#### **PURPOSE**

Purpose

Antiemetic

#### **INDICATIONS & USAGE**

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

#### **WARNINGS**

Warnings

Do not use in children under 12 years of age unless directed by a doctor

Ask a doctor before use if you have

glaucoma

a breathing problem such as emphysema or chronic bronchitis

trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use it you are taking sedatives or tranquilizers.

When using this product

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 the poison control center immediately.

#### **DOSAGE & ADMINISTRATION**

Directions

Dosage should be taken one hour before travel starts

Adults and children 12 years of age and older: Chew 1-2 tablets once daily, or as directed by a doctor

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

#### STORAGE AND HANDLING

Other information

Phenylketonurics: Contains Phenylalanine 0.28 mg per tablet Store at room temperature in a dry place Keep lid tightly closed

#### **INACTIVE INGREDIENT**

nactive ingredients

aspartame, croscarmellose sodium, dextrose, FD&C Red #40 Lake, magnesium stearate, maltodextrin, microcrystalline cellulose, natural and artificial flavors, silicon dioxide, sodium sulfate, sugar, tricalcium phosphate.

#### **QUESTIONS**

Questions or comments? call 1-800-645-2158

#### OTHER SAFETY INFORMATION

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

#### SPL UNCLASSIFIED SECTION

Distributed by: Rugby Laboratories

17177 N. Laurel Park Drive, Suite 233, Livonia, MI 48152

#### Keep out of reach of children.

In case of overdose, get medical help or contact the poison control center immediately.

#### PRINCIPAL DISPLAY PANEL

# MECLIZINE HCL CHEWABLES

Rx Only

30 Tablets

Lot: 43716 1

Exp: 09/16

Usual adult dosage: See package insert
Store at controlled room temperature: Room Temperature Mfg. for: Rugby Laboratories Livonia, Mi 48150 Ø536 - I @18 - I @ Dist. by: Redpharm Drug Eden Prairie MN 55344

LCN: 662947



rugby travel sickness tablet, chewable

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67296-1128(NDC:0536-1018)	
Route of Administration	ORAL			

### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
0	S	

MECLIZINE HYDRO CHLO RIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570) MECLIZINE HYDRO CHLO RIDE 25 mg

Inactive Ingredients		
Ingredient Name	Strength	
ASPARTAME (UNII: Z0H242BBR1)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
<b>DEXTROSE</b> (UNII: IY9 XDZ35W2)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MALTO DEXTRIN (UNII: 7CVR7L4A2D)		
SODIUM SULFATE (UNII: 0 YPR65R21J)		
SUCROSE (UNII: C151H8M554)		
TRICALCIUM PHO SPHATE (UNII: K4C08 XP666)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		

Product Characteristics			
Color	pink	Score	2 pieces
Shape	ROUND (Biconvex Uncoated Tablet with Bisect)	Size	8 mm
Flavor		Imprint Code	21G
Contains			

l	Packaging			
l	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
ı	1 NDC:67296-1128-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/19/2014	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	08/19/2014	

## Labeler - RedPharm Drug, Inc. (828374897)

Establishment			
Name	Address	ID/FEI	Business Operations
RedPharm Drug, Inc.		828374897	repack(67296-1128), relabel(67296-1128)

Revised: 1/2020 RedPharm Drug, Inc.