

RUGBY- rugby tablet
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.

SPL UNCLASSIFIED SECTION

Drug Facts

ACTIVE INGREDIENT

Active ingredient (in each caplet)

Meclizine HCl, USP 12.5 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 if 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: take 2-4 caplets 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

Each Caplet Contains: Calcium 25 mg
store at room temperature in a dry place
Keep lid tightly closed

INACTIVE INGREDIENT

Inactive ingredients

croscarmellose sodium, dicalcium phosphate dihydrate, magnesium stearate, microcrystalline cellulose, silicon dioxide, sodium sulfate, stearic acid.

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

www.rugbylaboratories.com

OTC KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF THE REACH OF CHILDREN

PRINCIPAL DISPLAY PANEL

NDC: 67296-1252-3
MECLIZINE HCL
12.5MG
30 Caplets

Rx Only

Lot: 46602 1

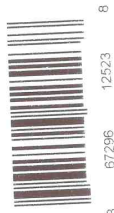
Exp: 10/17

Usual adult dosage: See package insert
Store at controlled room temperature 20-25 C (68-77 F)

Mfg. For: Rugby Laboratories
Livonia, MI 48150
0536-1017-01

Dist. by: Redpharm Drug, Eden Prairie, MN 55344

SIN 892295



rugby tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67296-1252(NDC:0536-1017)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	12.5 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
SODIUM SULFATE (UNII: 0YPR65R21J)	

Product Characteristics

Color	white	Score	2 pieces
Shape	CAPSULE (modified capsule shaped uncoated tablet with bisect)	Size	3mm
Flavor		Imprint Code	19G
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67296-1252-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	03/07/2014	

Labeler - RedPharm Drug, Inc. (828374897)

Establishment

Name	Address	ID/FEI	Business Operations
RedPharm Drug Inc.		828374897	relabel(67296-1252) , repack(67296-1252)

