

MECLIZINE- meclizine hcl 12.5 mg tablet
RUGBY LABORATORIES

Drug Facts

Active ingredient (in each caplet)

Meclizine HCl 12.5 mg

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

- dosage should be taken one hour before travel starts

adults and children 12 years and over	take 2 or 4 caplets once daily or as directed by a doctor
--	--

Other information

- each caplet contains: **calcium 28 mg**
- store at 20°-25°C (68°-77°F)

Inactive ingredients

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

Questions or comments?

(866) 562-2756 (Mon-Fri 8 AM to 4 PM EST)

Rugby®

NDC 0536-1297-10

Meclizine

12.5mg

Antiemetic

1000 Caplets

Rugby® NDC 0536-1297-10

Meclizine
12.5 mg

Actual Size
PH049

Antiemetic
1000 Caplets

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

Drug Facts

Active ingredient (in each caplet)
Meclizine HCl 12.5 mg

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 (800-222-1222).

Directions

- dosage should be taken one hour before travel starts

 adults and children
 take 2 or 4 caplets once daily or as
 12 years and over
 directed by a doctor

Other information

- each caplet contains: calcium 28 mg ■ store at 20°-25°C (68°-77°F)

Inactive ingredients croscarmellose sodium, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid

Questions or comments? (800) 562-2756 (Mon-Fri 8 AM to 4 PM EST)

Distributed by:
RUGBY® LABORATORIES
 Indianapolis, IN 46208
 www.majopharmaceuticals.com
 (800) 616-2471

Rev. 07/24 R-111
 Re-order No. 371030

SPOT UV

MECLIZINE

meclizine hcl 12.5 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1297
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	2 pieces
Shape	CAPSULE (CAPSULE SHAPED TABLET)	Size	13mm
Flavor		Imprint Code	PH049
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1297-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/21/2020	
2	NDC:0536-1297-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M009	05/21/2020	

Labeler - RUGBY LABORATORIES (079246066)**Registrant** - Pharbest Pharmaceuticals, Inc. (557054835)**Establishment**

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	analysis(0536-1297) , manufacture(0536-1297) , pack(0536-1297)

