

MECLIZINE- meclizine hcl 12.5 mg tablet
RUGBY LABORATORIES

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.

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
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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?

1-800-645-2158

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

THIS PACKAGE FOR HOUSEHOLD WITHOUT YOUNG CHILDREN

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

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Questions or comments? 1-800-645-2158
www.rugbylaboratories.com

Distributed by:
RUGBY® LABORATORIES
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Suite 233
Livonia, MI 48152

Rev. 05/20 R-111 Re-order No. 371030



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Orig. 05/20

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 final	part336	05/21/2020		

Labeler - RUGBY LABORATORIES (079246066)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment

Name	Address	ID/FEI	Business Operations
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Pharbest Pharmaceuticals,
Inc.

557054835

analysis(0536-1297) , manufacture(0536-1297) , pack(0536-1297)

Revised: 12/2022

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