

RUGBY MECLIZINE HCL- meclizine hydrochloride tablet, film coated
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.

MECLIZINE HCl, USP 12.5 mg CAPLETS

Drug Facts

Active ingredient (in each caplet)

Meclizine HCl, USP 12.5 mg

Purpose

Antiemetic

Uses

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

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 a Poison Control Center immediately.

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

Other information

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

Inactive ingredients

croscarmellose sodium, dicalcium phosphate dihydrate, hypromellose, magnesium stearate,

microcrystalline cellulose, propylene glycol, silicon dioxide, sodium sulfate, stearic acid, titanium dioxide.

Questions or comments?

Call 1-800-645-2158

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

Distributed by: **Rugby Laboratories**

17177 N. Laurel Park Drive, Suite 233

Livonia, MI 48152

www.rugbylaboratories.com

Rugby®

NDC 0536-1178-01

NEW FORMULA AND APPEARANCE

Meclizine HCl, USP

12.5 mg Each

ANTIEMETIC

100 CAPLETS

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Uses prevents and treats nausea, vomiting or dizziness due to motion sickness	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	When using this product Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers. • may cause drowsiness • alcohol, sedatives, and tranquilizers may increase drowsiness

Drug Facts (continued under label)
TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING
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FRESH

Drug Facts (continued) • 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 immediately.	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	Other information • Each Caplet Contains: Calcium 25 mg • Store at room temperature in a dry place • Keep lid tightly closed	Inactive ingredients crosscarmellose sodium, calcium phosphate dihydrate, hydroxyethylcellulose, magnesium stearate, microcrystalline cellulose, propylene glycol, silicon dioxide, sodium sulfate, stearic acid, titanium dioxide.	Questions or comments? Call 1-800-645-2158
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RUGBY MECLIZINE HCL

meclizine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1178
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
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (Film Coated)	Score	2 pieces
Shape	CAPSULE (Modified)	Size	13mm
Flavor		Imprint Code	19G
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1178-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/20/2018	07/31/2022
2	NDC:0536-1178-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/20/2018	07/31/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	04/20/2018	07/31/2022

Labeler - RUGBY LABORATORIES (079246066)