

MECLIZINE HCL 12.5 MG- meclizine hcl 12.5 mg tablet
RPK Pharmaceuticals, 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.

Meclizine HCL 12.5

Drug Facts

Active ingredient (in each caplet)

Meclizine HCL 12.5 mg

Purpose

Antiemetic

Uses

- prevents and treats nausea, vomiting, or dizziness due to motion sickness
- for other uses, consult your doctor

Warnings

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

- you may get drowsy
- avoid alcoholic drinks
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful 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.

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

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Directions

- **adults & children 12 years and over:** 2-4 caplets once daily
- **children under 12 years:** ask a doctor

Other information

- **each caplet contains:** calcium 51 mg
- store at room temperature 15°-30°C (59°-86°F)
- This is a bulk package. Dispense contents with a child-resistant closure in a tight, light-resistant container as defined in the USP.

Inactive ingredients

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

Questions or comments?

call **516-341-0666**, 8:30 am - 4:30 pm ET, Monday - Friday

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

Distributed by: **Reliable 1 Laboratoires LLC, Valley Stream, NY 11580**

www.reliable1labs.com

HOW SUPPLIED

Product: 53002-6060

NDC: 53002-6060-1 10 TABLET in a BOTTLE

NDC: 53002-6060-2 20 TABLET in a BOTTLE

NDC: 53002-6060-3 30 TABLET in a BOTTLE

Meclizine HCl 12.5mg Tablets



MECLIZINE HCL 12.5 MG

meclizine hcl 12.5 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53002-6060(NDC:69618-027)
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	

Product Characteristics

Color	white	Score	2 pieces
Shape	OVAL	Size	13mm
Flavor		Imprint Code	AP;117
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53002-6060-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	
2	NDC:53002-6060-1	10 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	
3	NDC:53002-6060-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	



MECLIZINE HCL 12.5 MG CAPLET

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	11/01/2015	

Labeler - RPK Pharmaceuticals, Inc. (147096275)

Establishment

Name	Address	ID/FEI	Business Operations
RPK Pharmaceuticals, Inc.		147096275	RELABEL(53002-6060) , REPACK(53002-6060)

Revised: 12/2020

RPK Pharmaceuticals, Inc.