

MECLIZINE HCL 25 MG- meclizine hydrochloride tablet, chewable
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 25 mg Chewable Tablets

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

Drug Facts

Active ingredient (in each chewable tablet)

Meclizine HCl, USP 25 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 the poison control center immediately.

Directions

- dosage should be taken one hour before travel starts.
- **adults and children 12 years of age and older:** Chew 1-2 tablets 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

- phenylketonurics: contains phenylalanine 0.28 mg per tablet
- store at room temperature in a dry place

Inactive ingredients Aspartame, croscarmellose sodium, dextrose, FD&C red #40 lake, magnesium stearate, maltodextrin, microcrystalline cellulose, natural and artificial flavors, silicon dioxide, sodium

sulfate, sugar, tricalcium phosphate.

Questions? If you have any questions or comments or to report an adverse event, please contact **(800) 795-9775**.

Distributed by: Plus Pharma, Commack, NY 11725

*Plus Pharma is not affiliated with the owner of the registered trademark Bonine®.

HOW SUPPLIED

Product: 53002-7650

NDC: 53002-7650-1 10 TABLET, CHEWABLE in a BOTTLE

NDC: 53002-7650-2 20 TABLET, CHEWABLE in a BOTTLE

NDC: 53002-7650-3 30 TABLET, CHEWABLE in a BOTTLE

Meclizine 25mg Chewtabs



MECLIZINE HCL 25 MG

meclizine hydrochloride tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53002-7650(NDC:51645-994)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
SUCROSE (UNII: C151H8M554)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	

DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	

Product Characteristics

Color	pink (Uncoated)	Score	2 pieces
Shape	ROUND (Biconvex)	Size	8mm
Flavor	RASPBERRY	Imprint Code	21G
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53002-7650-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	
2	NDC:53002-7650-1	10 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	
3	NDC:53002-7650-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	10/15/2015	

Labeler - RPK Pharmaceuticals, Inc. (147096275)

Establishment

Name	Address	ID/FEI	Business Operations
RPK Pharmaceuticals, Inc.		147096275	RELABEL(53002-7650) , REPACK(53002-7650)

Revised: 12/2020

RPK Pharmaceuticals, Inc.