

MECLIZINE HYDROCHLORIDE- meclizine hydrochloride tablet, chewable
PD-Rx 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.

Drug Facts

Active ingredient (in each chewable tablet)

Meclizine HCl 25 mg

Purpose

Antiemetic

Uses

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

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

- 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 of age and over	chew 1 to 2 tablets once daily, or as directed by a doctor
children under 12 years of age	do not give this product to children under 12 years of age unless directed by a doctor

Other information

□ Each tablet contains 0.09 mg of Magnesium and 0.82 mg of Sodium

□ Store in a dry place

□ keep lid tightly closed

Croscarmellose Sodium, Crospovidone, FD&C Red #40 Lake, French Vanilla Flavor, Lactose, Magnesium Stearate, Raspberry Flavor, Silica, Sodium Saccharin, Stearic Acid

Questions or comments?

1-800-645-2158

TAMPER EVIDENT: DO NOT USE IF SEAL IS BROKEN OR MISSING FROM BOTTLE.

*This product is not manufactured or distributed by Wellspring Pharmaceutical Corporation, owner of the registered trademark Bonine®.

HOW SUPPLIED

Each round chewable pink scored tablet imprinted with 5172 has a vanilla raspberry smell.

Bottles of 12 NDC 72789-250-12

Bottles of 20 NDC 72789-250-20

Bottles of 30 NDC 72789-250-30

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].


Keep container tightly closed. Dispense in a tight, light-resistant container, as defined in the USP using a child-resistant closure.

Meclizibe 25 mg

Antiemetic

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NDC 72789-250-20



Meclizine

Chewable

25 mg

Antiemetic

20 Tablets

TAMPER EVIDENT: DO NOT USE IF SEAL IS BROKEN OR MISSING FROM BOTTLE.

Inactive ingredients Croscarmellose Sodium, Crospovidone, FD&C Red #40 Lake, French Vanilla Flavor, Lactose, Magnesium Stearate, Raspberry Flavor, Silica, Sodium Saccharin, Stearic Acid.

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

Questions or comments?
1-800-645-2158

Marketed and Packaged by:
PD-Rx Pharmaceuticals, Inc
Oklahoma City, OK 73127
1-405-942-3040 v.8.19.0

GTIN: 00372789250205
SNO: E22A50000033
EXP: 01/2024
LOT: E22A50

MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72789-250(NDC:0536-1299)
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
CROSPROVIDONE (UNII: 2S7830E561)	
VANILLA (UNII: Q74T35078H)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
RASPBERRY (UNII: 4N14V5R27W)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics

Color	pink (Rosy)	Score	2 pieces
Shape	ROUND	Size	9mm
Flavor	VANILLA, RASPBERRY	Imprint Code	5172
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72789-250-12	12 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/05/2022	
2	NDC:72789-250-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/05/2022	
3	NDC:72789-250-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/05/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M009	10/30/2020	

Labeler - PD-Rx Pharmaceuticals, Inc. (156893695)

Registrant - PD-Rx Pharmaceuticals, Inc. (156893695)

Establishment

Name	Address	ID/FEI	Business Operations
PD-Rx Pharmaceuticals, Inc.		156893695	repack(72789-250)

Revised: 2/2023

PD-Rx Pharmaceuticals, Inc.