MECLIZINE 25- 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.

Meclizine 25

Drug Facts

Active Ingredients (in each chewable tablet)

Meclizine 25 mg

Purpose

Antiemetic

Indications and Usage

prevents and treats nausea, vomiting, dizziness associated with motion sickness:

Warnings

- **Do not use** for children under 12 years of age unless directed by a doctor.

Do not take unless directed by a doctor if you have

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Do not take if you are taking sedatives or tranquilizers, without first consulting your doctor.

When using this product

- do not exceed recommended dosage
- drowsiness may occur
- 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 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 1 hour befor travel starts.

Adults and children 12 years and over:	Take 1 or 2 tablets once daily, or as directed by doctor.

Inactive ingredients

Croscarmellose sodium, dextrose, FD& C Red #40, flavor, magnesium stearate, microcrystalline cellulose, silicon dioxide, sodium saccharine, stearic acid

Questions?

Adverse drug event call (866) 562-2756 (M-F, 8AM-4PM EST).

How Supplied

Meclizine 25mg are supplied as chewable pink round scored tablets with PH 051 embossed on them.

Supplied in bottles of 6, 12 , 20, 30 and 100 chewable tablets.

PRINCIPAL DISPLAY PANEL - 25 mg Bottle Label

Antiemetic

Each chewable tablet contains:

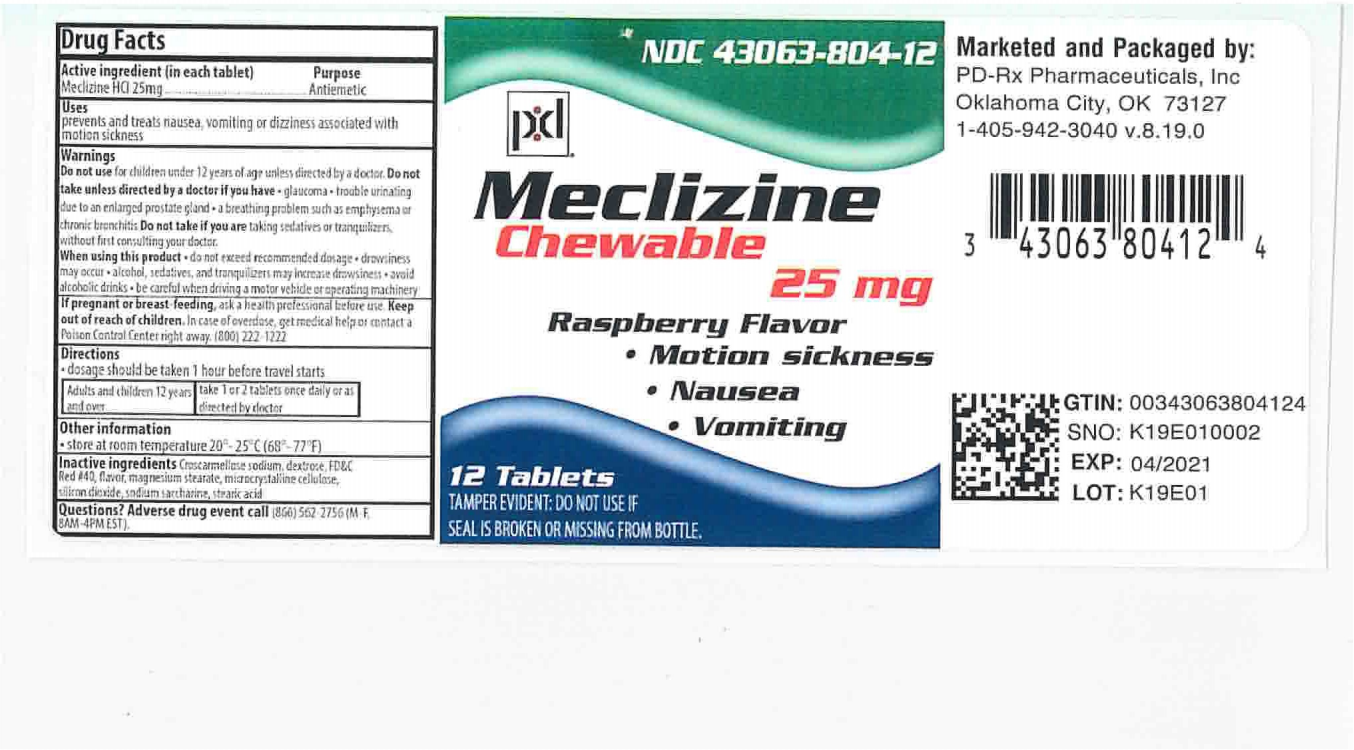
Meclizine HCl

25 mg

Store at 68°-77°F (20°-25°C)

Tamper evident by foil seal under cap.

Do not use if foil seal is broken or missing.



MECLIZINE 25

meclizine hydrochloride tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43063-804
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**
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DEXTROSE (UNII: IY9XDZ35W2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	PH;051
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43063-804-12	12 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/27/2017	11/30/2027
2	NDC:43063-804-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/12/2018	11/30/2027
3	NDC:43063-804-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2018	11/30/2027
4	NDC:43063-804-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/2018	11/30/2027
5	NDC:43063-804-06	6 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/23/2018	11/30/2027

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	11/27/2017	11/30/2027

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(43063-804)

Revised: 12/2021 PD-Rx Pharmaceuticals, Inc.