MECLIZINE 25- meclizine hydrochloride tablet, chewable
PD-Rx Pharmaceuticals, Inc.

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:

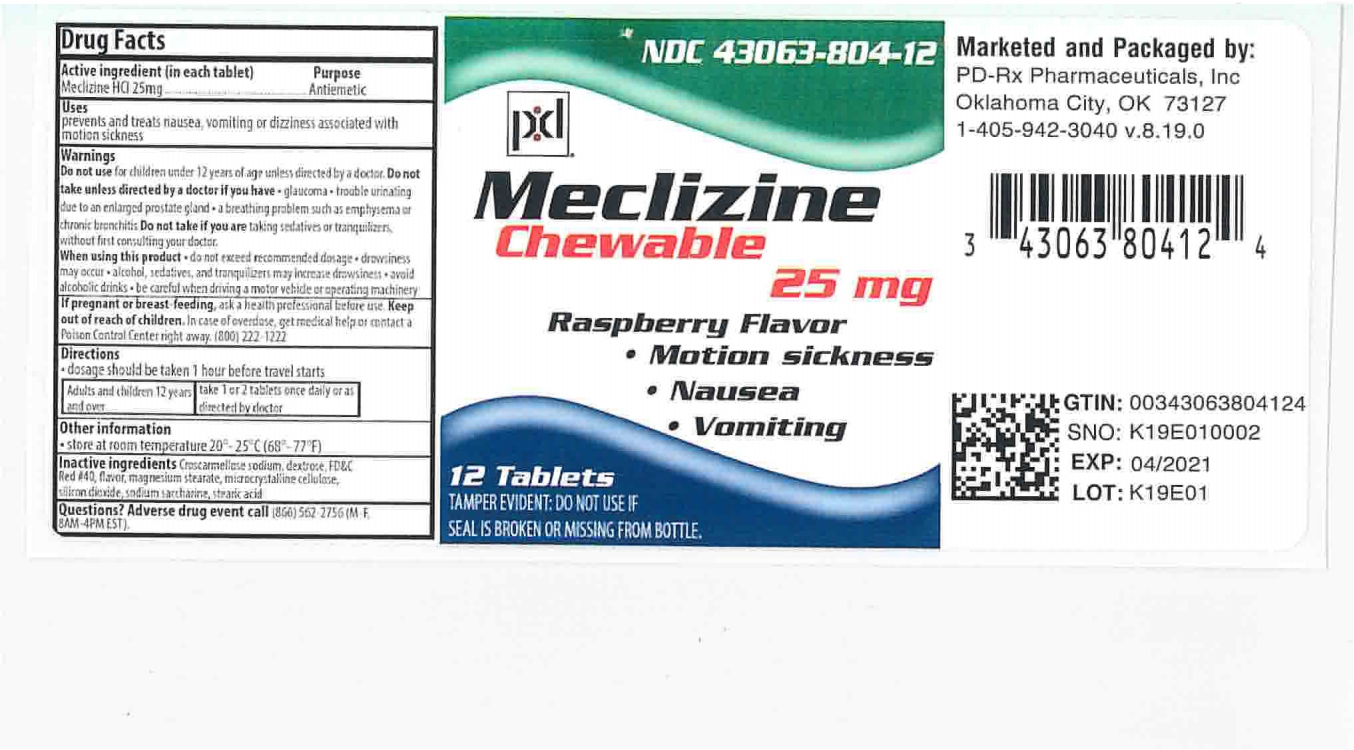
Meclizine HCl

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(NDC:16103-387)
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	pink (LIGHT PINK COLOR)	**Score**	2 pieces
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	PH051
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	
2	NDC:43063-804-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/12/2018	
3	NDC:43063-804-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2018	
4	NDC:43063-804-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/2018	
5	NDC:43063-804-06	6 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/23/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M009	11/27/2017	

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: 2/2024 PD-Rx Pharmaceuticals, Inc.