MECLIZINE HCL- meclizine hydrochloride chewable tablet, chewable Drug Ocean LLC

MECLIZINE HYDROCHLORIDE CHEWABLE TABLETS 25 MG

DRUG FACTS

Active Ingredients (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 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 0.0025 mg per tablet
- Store at room temperature in a dry place
- Keep lid tightly closed

Inactive ingredients

aspartame, colloidal silicon dioxide, croscarmellose sodium, dextrose, lake of FD & C Red 40, magnesium stearate, maltodextrin, microcrystalline cellulose, raspberry flavor, sodium sulfate anhydrous, sucrose, tribasic calcium phosphate

Questions or Comments?

Call 1-844-200-6566 Monday to Friday 9 AM to 5 PM EST

TAMPER EVIDENT: DO NOT USE IF FOIL SEAL UNDER CAP, PRINTED WITH "SEALED for YOUR PROTECTION" IS BROKEN OR MISSING

Distributed by:



Drug Ocean LLC, 1 Bridge Plaza, North Central Road

6th Floor, Suite 675

Fort Lee, NJ 07024

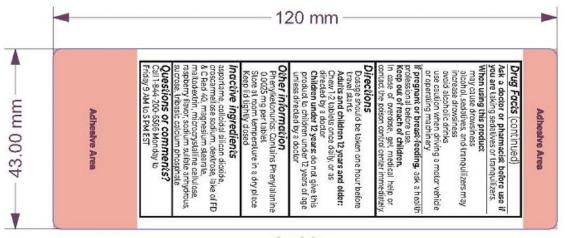
Manufactured by:

Unique Pharmaceutical Laboratories (A Div. of J. B. Chemicals & Pharmaceuticals Ltd.) Mumbai 400 030, India

ORG 12/23

PRINCIPAL DISPLAY PANEL - 25 mg Chewable Tablet Label

NDC 70985-010-01 Meclizine Hydrochloride Chewable Tablets 25mg (ANTIEMETIC) Travel Sickness 100 tablets



Inside



Outside

MECLIZINE HCL

meclizine hydrochloride chewable tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70985-010
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII: 3L5TQ84570)	MECLIZ INE HYDROCHLORIDE	25 mg	

Inactive Ingredients		
Ingredient Name	Strength	
SUCROSE (UNII: C151H8M554)		
ASPARTAME (UNII: Z0H242BBR1)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		

DEXTROSE (UNII: IY9XDZ 35W2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
RASPBERRY (UNII: 4N14V5R27W)	
SODIUM SULFATE ANHYDROUS (UNII: 36KCS0R750)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics			
Color	pink (Pink to light pink)	Score	2 pieces
Shape	ROUND	Size	8mm
Flavor	RASPBERRY	Imprint Code	M
Contains			

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:70985-010-	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/28/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M009	02/28/2022	

Labeler - Drug Ocean LLC (080381835)

Registrant - Unique Pharmaceutical Laboratories (917165052)

Establishment				
Name	Address	ID/FEI	Business Operations	
Unique Pharmaceutical Laboratories		650434645	manufacture(70985-010)	

Revised: 12/2023 Drug Ocean LLC