MECLIZINE HCL- meclizine hydrochloride tablet
Drug Ocean LLC

MECLIZINE HYDROCHLORIDE TABLETS, 12.5 mg

DRUG FACTS

Active Ingredients (in each tablet)

Meclizine HCl, USP 12.5 mg

Purpose

Antiemetic

Uses:

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

Warnings:

Do not take this product, unless directed by a doctor, if you have

- Glaucoma
- A breathing problem such as emphysema or chronic bronchitis
- Trouble urinating due to an enlarged prostate gland.

Do not use in children under 12 years of age unless directed by a doctor.

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

When using 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

Directions

- dosage should be taken one hour before travel starts

adults and children 12 years and over	take 2 or 4 tablets once daily or as directed by a doctor

Other Information

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

Inactive ingredients

colloidal silicon dioxide, crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose

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 - 12.5 mg Tablet Label

NDC 70985-009-01

Meclizine HCl

12.5 mg

100 Tablets

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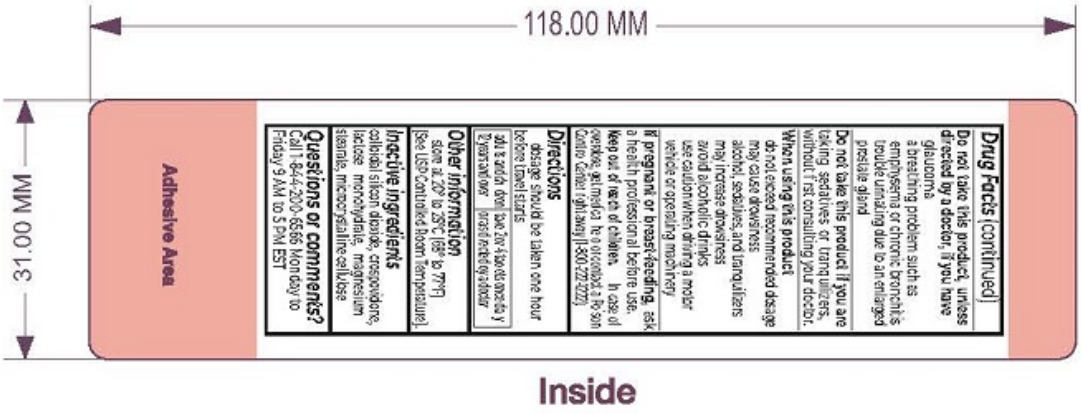
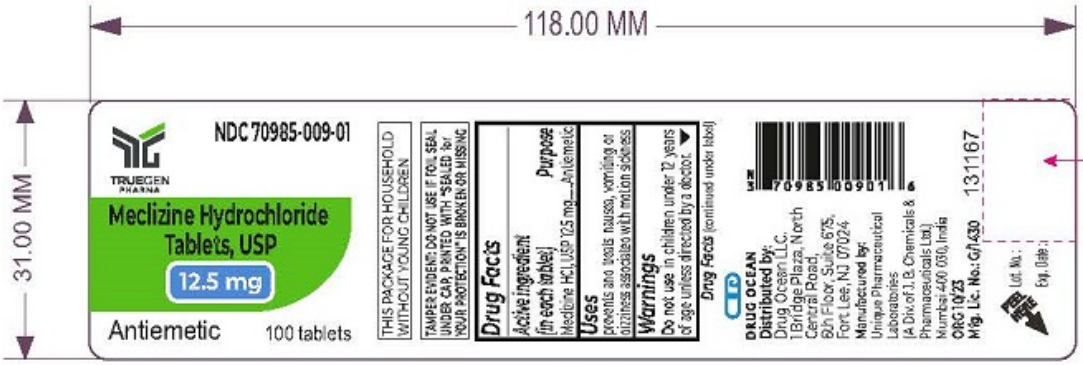


Inside



Outside

Unvarnish Area
(17 x 11 mm)

MECLIZINE HCL

meclizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70985-009
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	12.5 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPOVIDONE (UNII: 2S7830E561)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	white (White to Off White)	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	AB;12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70985-009-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M009	06/25/2021	

Labeler - Drug Ocean LLC (080381835)

Registrant - Drug Ocean LLC (080381835)

Establishment

Name	Address	ID/FEI	Business Operations
Unique Pharmaceutical Laboratories		650434645	manufacture(70985-009)

Revised: 12/2023 Drug Ocean LLC