MECLIZINE HCL- meclizine hydrochloride tablet
BluePoint Laboratories

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 HYDROCHLORIDE TABLETS, USP 12.5 mg

Drug Facts

Active ingredient (in each tablet)

Meclizine HCl, USP 12.5 mg

Purpose

Antiemetic

Uses

prevents and treats nausea, vomiting or dizziness associated with motion sickness.

Warnings

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

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 take this product if you are

taking sedatives or tranquilizers,

without first consulting your doctor.

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 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

Questions or comments?

Call 1-844-474-7464 Monday to Friday 8 AM - 5 PM ET

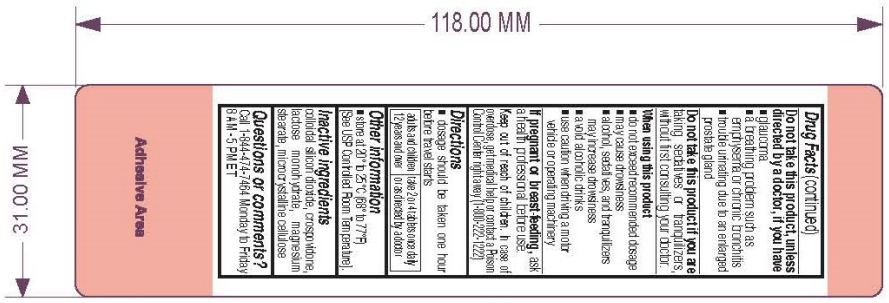
PRINCIPAL DISPLAY PANEL - 12.5 mg Tablet Label

NDC 68001-528-00

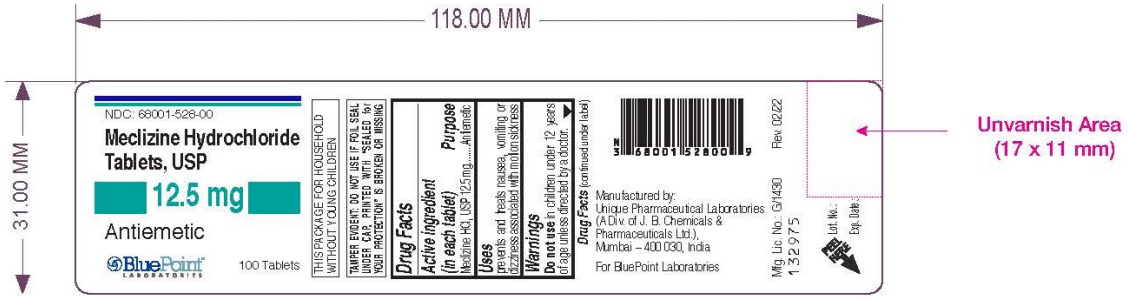
Meclizine Hydrochloride Tablets, USP

12.5 mg

100 Tablets



Inside



Outside

MECLIZINE HCL

meclizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68001-528
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:68001-528-00	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	03/14/2022	

Labeler - BluePoint Laboratories (985523874)

Registrant - Unique Pharmaceutical Laboratories (917165052)

Establishment

Name	Address	ID/FEI	Business Operations
Unique Pharmaceutical Laboratories		650434645	manufacture(68001-528)

Revised: 3/2022 BluePoint Laboratories