MECLIZINE- meclizine hcl 12.5 mg tablet Advanced Rx LLC

Active ingredient (in each caplet)

Meclizine HCl 12.5mg

Purpose

Antiemetic

Uses

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

Warnings

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

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

When using this product

- do not exceed recommended dosage
- drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful 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 1 hour before travel starts

Other information

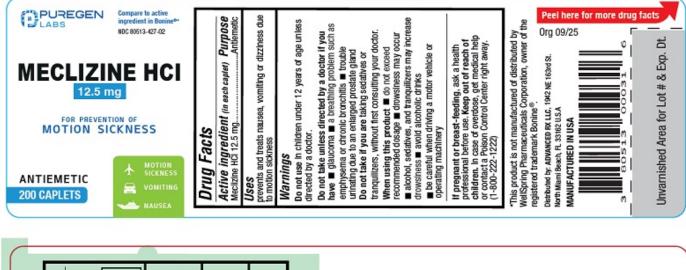
- Tamper Evident: do not use if safety seal under cap is broken or missing
- each caplet contains: calcium 28 mg
- store at room temperature 20°-25°C (68°-77°F).

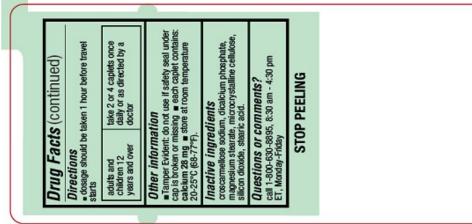
Inactive ingredients

croscarmellose sodium, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid.

Questions or comments?

call 1-800-630-8895, 8:30 am - 4:30 pm ET, Monday-Friday





MECLIZINE

meclizine hcl 12.5 mg tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80513-427
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZ INE HYDROCHLORIDE	12.5 mg	

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
STEARIC ACID (UNII: 4ELV7Z65AP)			

Product Characteristics			
Color	white	Score	2 pieces
Shape	CAPSULE (CAPSULE SHAPED TABLET)	Size	13mm
Flavor		Imprint Code	PH049
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80513- 427-02	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M009	09/01/2025	

Labeler - Advanced Rx LLC (042795108)

Registrant - Advanced Rx LLC (042795108)

Establishment				
Name	Address	ID/FEI	Business Operations	

Pharbest Pharmaceuticals, Inc. 557054835 manufacture(80513-427)

Revised: 9/2025 Advanced Rx LLC