MECLIZINE- meclizine hcl 12.5 mg tablet
A-S Medication Solutions

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.

Drug Facts

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 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
- 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.

Directions

- dosage should be taken 1 hour before travel starts

Adults and children 12 years and over	take 2 or 4 caplets once daily or as directed by doctor

Other information

- **Tamper Evident:** do not use if safety seal under cap is broken or missing
- 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?

Adverse drug event call (866) 562-2756 (M - F, 8AM - 4PM EST).

HOW SUPPLIED

Product: 50090-3017

NDC: 50090-3017-3 30 TABLET in a BOTTLE

NDC: 50090-3017-7 28 TABLET in a BOTTLE

NDC: 50090-3017-8 90 TABLET in a BOTTLE

Meclizine HCl 12.5 mg

MECLIZINE

meclizine hcl 12.5 mg tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50090-3017(NDC:16103-386)
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	white	**Score**	no score
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:50090-3017-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2018	
2	NDC:50090-3017-7	28 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2018	
3	NDC:50090-3017-8	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/09/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	02/01/2018	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-3017) , REPACK(50090-3017)

Revised: 5/2020 A-S Medication Solutions