

**MECLIZINE- meclizine hcl 12.5 mg tablet**  
**SDA Laboratories, Inc.**

*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.*

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**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**

- doage 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
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**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 (800) 687-0176 (M - F, 8AM - 4PM EST).**

**NDC 66424-0386-10**

**MECLIZINE**

**Meclizine HCl 12.5mg**

**Anti-Emetic**

- **Motion Sickness • Nausea • Vomiting**

**1000 CAPLETS**

**SDA**

**LABORATORIES**

NDC 66424-0386-10

**MECLIZINE**  
Meclizine HCl 12.5mg

**Anti-Emetic**



■ Motion Sickness ■ Nausea ■ Vomiting

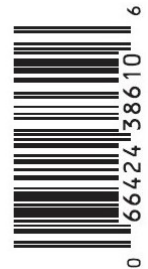
1000 CAPLETS

**SDA**  
LABORATORIES

This package for household without young children

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<b>Active ingredient (in each caplet)</b> Meclizine HCl 12.5mg.....Antiemetic	
<b>Uses</b> prevents and treats nausea, vomiting or dizziness associated with motion sickness	
<b>Warnings</b> 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.	
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Distributed by:  
SDA Laboratories, Inc., Greenwich, CT 06830  
**MADE IN USA**  
Org 02/15



**MECLIZINE**

meclizine hcl 12.5 mg tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66424-386
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44C1O) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE 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 (WHITE COLOR)	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:66424-386-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2018	
2	NDC:66424-386-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2018	

## Marketing Information

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

**Labeler** - SDA Laboratories, Inc. (948067889)

**Registrant** - Pharbest Pharmaceuticals, Inc. (557054835)

## Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(66424-386) , pack(66424-386) , analysis(66424-386)

Revised: 2/2018

SDA Laboratories, Inc.