

**MECLIZINE- meclizine hcl 25mg tablet, chewable**  
**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 tablet)**

Meclizine HCl 25mg

**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 1 or 2 tablets 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, dextrose, FD&C Red#40, flavor, magnesium stearate, microcrystalline cellulose, silicon dioxide, sodium saccharine, stearic acid

**Questions?**

**Adverse drug event call (800) 687-0176 (M - F, 8AM - 4PM EST).**

**NDC 66424-0387-01**

**\*Compare to the active ingredient in Bonine®**

**MECLIZINE**

**CHEWABLE**

**Raspberry Flavor**

**Meclizine HCl 25mg**

**Anti-Emetic**

**• Motion Sickness • Nausea • Vomiting**

**100 TABLETS**

**SDA**

**LABORATORIES**

NDC 66424-0387-10  
 \*Compare to active ingredient in Bonine®

**MECLIZINE  
 CHEWABLE**  
 Raspberry Flavor  
 Meclizine HCl 25mg  
**Anti-Emetic**

■ Motion Sickness ■ Nausea ■ Vomiting

1000 TABLETS  
**SDA**  
 LABORATORIES

This package for household without young children

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<b>Active ingredient (in each tablet)</b> Meclizine HCl 25mg.....	Antiemetic
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<b>QUESTIONS?</b> Adverse drug event call (800) 687-0176 (M - F, 8AM - 4PM EST).	

\*This product is not manufactured or distributed by Wellspring Pharmaceuticals Corporation, owner of the registered trademark Bonine.  
 Distributed by:  
 SDA Laboratories, Inc., Greenwich, CT 06830  
 MADE IN USA  
 Org 02/15



<b>MECLIZINE</b>			
meclizine hcl 25mg tablet, chewable			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66424-387
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			

Ingredient Name		Basis of Strength	Strength	
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)		MECLIZINE HYDROCHLORIDE	25 mg	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)				
DEXTROSE (UNII: IY9XDZ35W2)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
<b>Product Characteristics</b>				
Color	pink (LIGHT PINK COLOR)	Score	2 pieces	
Shape	ROUND (ROUND TABLET)	Size	8mm	
Flavor		Imprint Code	PH051	
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66424-387-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2018	
2	NDC:66424-387-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2018	
<b>Marketing Information</b>				
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(66424-387) , pack(66424-387) , analysis(66424-387)