# MECLIZINE- meclizine hcl 12.5 mg tablet RUGBY 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.

-----

#### **Drug Facts**

### **Active ingredient (in each caplet)**

Meclizine HCl 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	take 2 or 4 caplets once daily
12 years and over	or as directed by a doctor

#### Other information

- each caplet contains: calcium 28 mg
- store at 20°-25°C (68°-77°F)

### **Inactive ingredients**

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

### Questions or comments?

1-800-645-2158

**Rugby**®

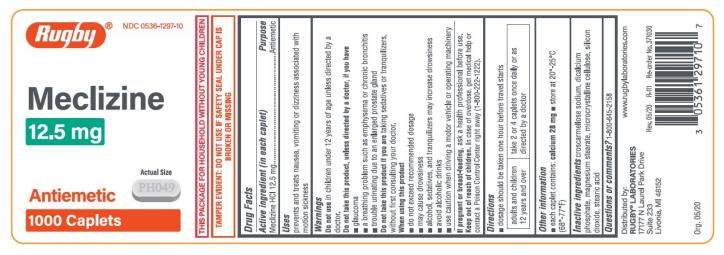
NDC 0536-1297-10

**Meclizine** 

12.5mg

**Antiemetic** 

1000 Caplets



### **MECLIZINE**

meclizine hcl 12.5 mg tablet

### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1297
Route of Administration	ORAL		

	Active Ingredient/Active Moiety		
ı	Ingredient Name	<b>Basis of Strength</b>	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			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:0536- 1297-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/21/2020	
l	2	NDC:0536- 1297-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/21/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	05/21/2020	

## Labeler - RUGBY LABORATORIES (079246066)

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

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations

Pharbest Pharmaceuticals, Inc. 557054835 analysis(0536-1297), manufacture(0536-1297), pack(0536-1297)

Revised: 12/2022 RUGBY LABORATORIES