# MECLIZINE HCL- meclizine hydrochloride tablets tablet Trigen 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.

-----

#### **DRUG FACTS**

## Active Ingredients (in each tablet)

Meclizine HCl 25 mg

### **Purpose**

Antiemetic

#### Uses:

prevents and treats nausea, vomiting, or dizziness due to motion sickness.• For other uses, consult your doctor.

## WARNING: Ask a doctor before use if you have

• Glaucoma • A breathing problem such as emphysema or chronic bronchitis • Trouble urinating due to an enlarged prostate gland.

#### KEEP OUT OF REACH OF CHILDREN

**Ask doctor or pharmacist before use if you are** taking sedatives or tranquilizers.

## When using product

• You may get drowsy • Avoid alcoholic drinks • Alcohol, sedatives and tranquilizers may increase drowsiness • Be careful when driving a motor vehicle or operating machinery

**If pregnant or breast feeding,** ask a Physician before use.

## Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

- Adults & children 12 years and over: 2-4 tablet once daily
- Children under 12 years: ask a doctor

## **Other Information**

• each tablet contains: calcium 51 mg

• Store at room temperature 15°-30°C (59°-86°F)

## **Inactive ingredients**

Microcrystalline cellulose, magnesium stearate, sodium starch glycolate, crospovidone, talc, and lactose.

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

#### **TRIGEN**

**LABORATORIES** 

## Manufactured for:

TRIGEN Laboratories, Inc., Sayreville, NJ 08872 www.trigenlab.com Rev. 08/13

## PRINCIPAL DISPLAY PANEL - 25 mg Tablet Label

NDC 13811-647-10

**Meclizine HCl** 

25 mg

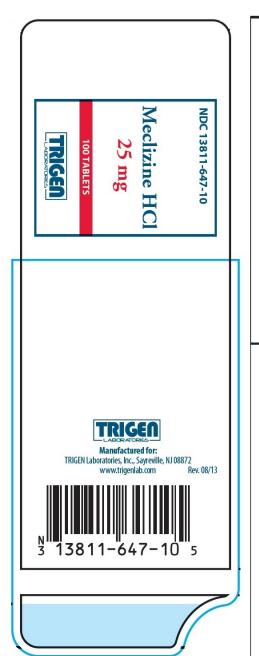
**100 TABLETS** 

**TRIGEN** 

**LABORATORIES** 

## Manufactured for:

TRIGEN Laboratories, Inc., Sayreville, NJ 08872 www.trigenlab.com Rev. 08/13



#### Drua Facts

Active Ingredients (in each tablet)...Purpose Meclizine HCl 25 mg . . . . . Antiemetic

**Uses:** prevents and treats nausea, vomiting, or dizziness due to motion sickness. • For other uses, consult your doctor.

## WARNING: Ask a doctor before use if you have

- Glaucoma A breathing problem such as emphysema or chronic bronchitis
- Trouble urinating due to an enlarged prostate gland.

#### **KEEP OUT OF REACH OF CHILDREN**

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

## TRIGEN Manufactured for:

TRIGEN Laboratories, Inc., Sayreville, NJ 08872 www.trigenlab.com Rev. 08/13



#### **Drug Facts** (continued)

Ask doctor or pharmacist before use if you are taking sedatives or tranquilizers.

**When using product** • You may get drowsy • Avoid alcoholic drinks

- Alcohol, sedatives and tranquilizers may increase drowsiness
- Be careful when driving a motor vehicle or operating machinery

**If pregnant or breast feeding,** ask a Physician before use.

#### Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions • Adults & children 12 years and over: 2-4 tablets once daily • Children under 12 years: ask a doctor

#### Other Information

- each tablet contains: calcium
- 51 mg
- Store at room temperature 15°-30°C (59°-86°F)

#### **Inactive ingredients**

Microcrystalline cellulose, magnesium stearate, sodium starch glycolate, crospovidone, talc, and lactose.



#### Manufactured for:

TRIGEN Laboratories, Inc., Sayreville, NJ 08872 www.trigenlab.com

Rev. 08/13

#### MECLIZINE HCL

meclizine hydrochloride tablets tablet

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:138 11-647(NDC:57631-008)

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

MECLIZINE HYDRO CHLO RIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570) MECLIZINE HYDRO CHLO RIDE 25 mg

Inactive Ingredients			
Ingredient Name	Strength		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)			
POVIDONE K30 (UNII: U725QWY32X)			
TALC (UNII: 7SEV7J4R1U)			
LACTOSE (UNII: J2B2A4N98G)			

Product Characteristics					
Color	WHITE	Score	no score		
Shape	OVAL	Size	13mm		
Flavor		Imprint Code	ET3		
Contains					

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:13811-647-10	100 in 1 BOTTLE				
2	NDC:13811-647-01	1000 in 1 BOTTLE				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part336	09/23/2013			

# **Labeler** - Trigen Laboratories, Inc. (830479668)

## Registrant - Trigen Laboratories, Inc.. (830479668)

Revised: 9/2013 Trigen Laboratories, Inc.