

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 caplet)

Meclizine HCl 12.5 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 caplets once daily
- **Children under 12 years:** ask a doctor

Other Information

- each caplet 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 - 12.5 mg Caplet Label

NDC 13811-646-10

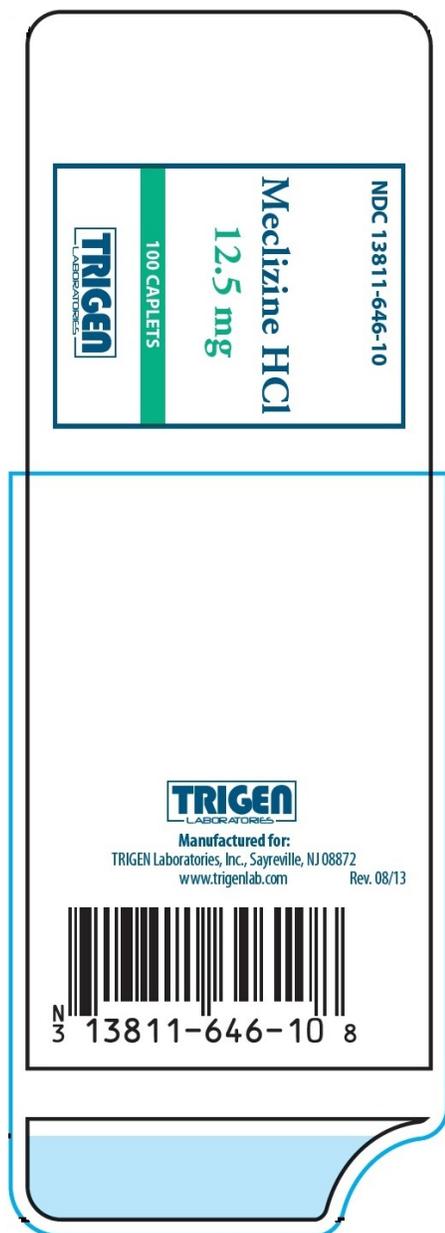
Meclizine HCl
12.5 mg

100 CAPLETS

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Drug Facts

N 3 13811-646-10 8

Drug Facts (continued)

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MECLIZINE HCL

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:138 11-646 (NDC:57631-007)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MECLIZINE HYDRO CHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	12.5 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (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	10mm
Flavor		Imprint Code	ET5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13811-646-10	100 in 1 BOTTLE		
2	NDC:13811-646-01	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.