

MECLIZINE HCL- meclizine hydrochloride chewable tablets tablet, chewable
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

• Take dose one hour before travel starts • Tablets can be chewed or swallowed whole with water • Adults & children 12 years and over: 1-2 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, lactose, Raspberry flavor, FD&C Red #40 lake, starch, sodium saccharin, and dextrates hydrated.

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 Chewable Tablet Label

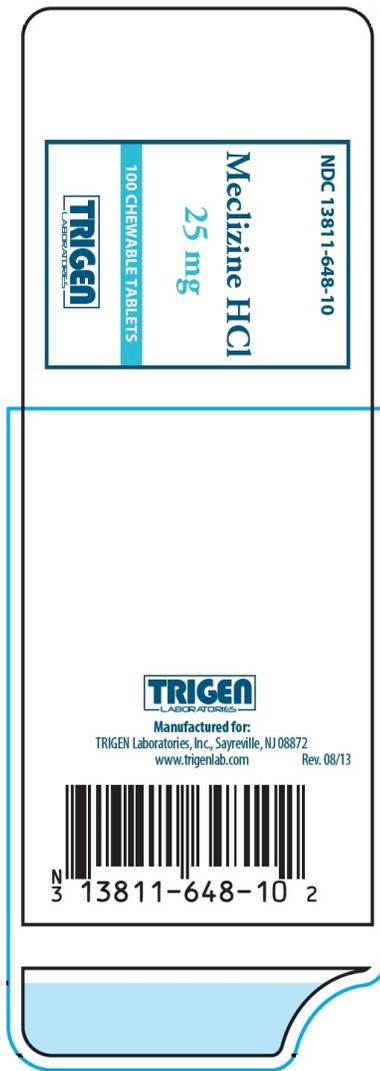
NDC 13811-648-10

Meclizine HCl

25 mg

100 CHEWABLE TABLETS

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Lift Here
to
Remove
Drug Facts

N 3 13811-648-10 2

Drug Facts (continued)

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MECLIZINE HCL

meclizine hydrochloride chewable tablets tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:138 11-648(NDC:57631-009)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
LACTOSE (UNII: J2B2A4N98G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
STARCH, CORN (UNII: O8232NY3SJ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
DEXTRATES (UNII: G263MI44RU)	

Product Characteristics

Color	PINK	Score	no score
Shape	ROUND	Size	8mm
Flavor	RASPBERRY	Imprint Code	ET1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13811-648-10	100 in 1 BOTTLE		
2	NDC:13811-648-01	1000 in 1 BOTTLE		

Marketing Information

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

Labeler - Trigen Laboratories, Inc. (830479668)

Registrant - Trigen Laboratories, Inc.. (830479668)

Revised: 9/2013

Trigen Laboratories, Inc.