MECLIZINE 25- meclizine hydrochloride tablet The Generic Pharmaceutical Company

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.

Meclizine 25

Drug Facts

Active Ingredients (in each immediate-release tablet)

Meclizine 25 mg

Purpose

Antiemetic

Indications and Usage

- For prevention and treatment of these symptoms associated with motion sickness:
 - nausea
 - vomiting
 - dizziness

Warnings

■ **Do not use** for children under 12 years of age unless directed by a doctor.

Ask a doctor before use if you have

- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- a breathing problem such as emphysema or chronic bronchitis

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

When using this product

- drowsiness may occur
- 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 health professional before use.

Keep out of reach of children.

In case of accidental overdose, seek medical help or contact a Poison Control Center immediately. 1-800-222-1222

Directions

Do not exceed recommended dosage.

To prevent motion sickness; take the first dose one hour before starting activity.

Adults and	1 to 2 tablets
children 12	once daily, or
years of age	as directed by
	a doctor.
and over.	a uocioi.

Inactive ingredients

Magnesium Stearate, Microcrystalline Cellulose, Sodium Starch Glycolate

Questions and comments?

Call 1-205-313-8298

Manufactured for The Generic Pharmaceutical Company, Inc. Leeds, AL 35094

PRINCIPAL DISPLAY PANEL - 25 mg Tablet Bottle Label

NDC 57963-101-01 100 Tablets

Meclizine 25

Antiemetic

Each immediate-release tablet contains: Meclizine HCl 25 mg

Store at 59°-86°F (15°-30°C) [see USP Controlled Room Temperature]. Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

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.....Antiemetic

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dizziness

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NDC 57963-101-01

100 Tablets

Meclizine 25

Antiemetic

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Facts (continued

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Control Center immediately. 1-800-222-1222

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NDC 57963-101-01

100 Tablets

Antiemetic

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Drug Facts (continued lestions and comments

Rev. 02/15

MECLIZINE 25

meclizine hydrochloride tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57963-101	
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

macuve ingredients		
Ingredient Name	Strength	
Magnesium Stearate (UNII: 70097M6I30)		
Microcrystalline Cellulose (UNII: OP1R32D61U)		
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)		

Product Characteristics

- 1 0 mar 6 0 mm m o 0 0 1 mm o			
Color	WHITE	Score	no score
Shape	OVAL	Size	13mm
Flavor		Imprint Code	MC
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57963-101- 01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part336	12/0 1/20 16	

Labeler - The Generic Pharmaceutical Company (078787060)

Revised: 1/2017 The Generic Pharmaceutical Company