

**MECLIZINE HYDROCHLORIDE- meclizine hcl tablet, chewable
NORTHEAST PHARMA**

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.

hpc 779

Active ingredient (in each chewable tablet)

Meclizine HCl 25 mg

Purpose

Antiemetic

Uses

For the 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
- breathing problems, such as emphysema or chronic bronchitis
- difficulty urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- alcohol, sedatives, and tranquilizers may increase drowsiness
- drowsiness may occur
- avoid alcoholic beverages
- 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.

Directions

- do not exceed recommended dose
- dosage should be taken one hour before travel starts
- chew or crush tablets completely before swallowing; do not swallow tablets whole
- adults and children 12 years and over: take 1 to 2 tablets once daily or as directed by a doctor

Other information

- **TAMPER EVIDENT:** Do not use if imprinted seal under cap is broken or missing.
- store at 20-25°C (68-77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from humidity

Inactive ingredients

corn starch, FD&C red #40 aluminum lake, flavor, lactose anhydrous, magnesium stearate, saccharin sodium, silicon dioxide

Questions or comments?

1-800-540-3765

Principal Display Panel

MECLIZINE HYDROCHLORIDE

meclizine hcl tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80136-779
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
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	pink	Score	2 pieces
Shape	ROUND	Size	9mm
Flavor	RASPBERRY	Imprint Code	44;404
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80136-779-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	11/01/2022	

Labeler - NORTHEAST PHARMA (081232935)**Registrant** - GERI-CARE PHARMACEUTICAL CORP (611196254)