

MECLIZINE HYDROCHLORIDE- meclizine hcl tablet
NORTHEAST PHARMA

hpc 778L (378)

Active ingredient (in each tablet)

Meclizine HCl 25mg

Purpose

Antiemetic

Uses

For the prevention and treatment of these symptoms associated with motion sickness •
nausea • vomiting • dizziness

Warnings

Do not use in children under 12 years of age unless directed by a doctor.

Ask a doctor before use if you have

- breathing problems, such as emphysema or chronic bronchitis
- glaucoma
- 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

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

- take the first dose 1/2 hour to 1 hour before starting activity
- **Adults and children 12 years of age and over:**

Take 1 to 2 tablets once daily, or as directed by a doctor
Do not exceed 2 tablets in 24 hours.

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

colloidal silicon dioxide, D&C yellow #10 lake, lactose monohydrate, magnesium stearate, pregelatinized starch.

Questions or comments?

1-800-540-3765

package label

| MECLIZINE HYDROCHLORIDE | | | |
|--|---|---------------------------|-----------------|
| meclizine hcl tablet | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:80136-378 |
| Route of Administration | ORAL | | |
| Active Ingredient/Active Moiety | | | |
| | Ingredient Name | Basis of Strength | Strength |
| | MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - | MECLIZINE | 25 mg |

UNII:3L5TQ84570)

HYDROCHLORIDE

25 mg

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6) | |

Product Characteristics

| | | | |
|----------|--------|--------------|----------|
| Color | yellow | Score | no score |
| Shape | ROUND | Size | 9mm |
| Flavor | | Imprint Code | 44;403 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:80136-378-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 05/01/2022 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M009 | 05/01/2022 | |

Labeler - NORTHEAST PHARMA (081232935)**Registrant** - Geri-Care Pharmaceutical Corp (611196254)

Revised: 11/2023

NORTHEAST PHARMA