MEDIQUE MEDI-MECLIZINE- meclizine hydrochloride tablet A-S Medication Solutions

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 ingredient (in each tablet)

Meclizine Hydrochloride 25 mg

Purpose

Antiemetic

Uses

For the prevention and treatment of the nausea, vomiting, or dizziness associated with motion sickness.

Warnings

Do not use

- for children under 12 years of age unless directed by a doctor
- for frequent or prolonged use except under the advice of a doctor

Ask a doctor before use if you have

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

if you are

taking sedatives or tranquilizers

When using this product

- drowsiness may occur
- alcohol, sedatives and tranquilizers may increase the drowsiness effect
- avoid alcoholic beverages while taking this product
- use caution when driving a motor vehicle or operating machinery

Do not exceed recommended dosage.

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 use more than directed
- to prevent motion sickness, take the first dose one hour before starting activity

Adults and children: (12 years and older) 1 to 2 tablets once daily or as directed by a doctor. Do not exceed 2 tablets in 24 hours.

Children under 12 years: Do not give to children under 12 years of age.

Other information

- store at room temperature 59- 86º F (15-30ºC)
- tamper-evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

anhydrous lactose, colloidal silicon dioxide, corn starch, D&C yellow # 10, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

Questions or comments?

1-800-634-7680

HOW SUPPLIED

Product: 50090-4493

NDC: 50090-4493-0 2 TABLET in a PACKET / 500 in a BOX

MECLIZINE HYDROCHLORIDE



MEDIQUE MEDI-MECLIZINE

meclizine hydrochloride tablet

Product Information

UNII:3L5TQ84570)

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50090-4493(NDC:47682-480)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength

MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - MECLIZINE - ME

HYDROCHLORIDE

Inactive Ingredients

Ingredient Name
Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)

SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)

STARCH, CORN (UNII: 08232NY3SJ)

D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)

MAGNESIUM STEARATE (UNII: 70097M6I30)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)

Product Characteristics

Color yellow (yellow) Score 2 pieces

Shape ROUND (ROUND) Size 9mm

Flavor Imprint Code TCL;086

Contains

Item Code Package Description Marketing Start Date Marketing End Date

1 NDC:50090-4493-0 500 in 1 BOX 08/30/2019

2 in 1 PACKET; Type 0: Not a Combination Product

| Marketing Information | | | | | |
|-----------------------|---|-------------------------|-----------------------|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | |
| OTC monograph final | part336 | 09/01/2013 | | | |
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Labeler - A-S Medication Solutions (830016429)

| Establishment | | | | | |
|--------------------------|---------|-----------|----------------------------|--|--|
| Na me | Address | ID/FEI | Business Operations | | |
| A-S Medication Solutions | | 830016429 | RELABEL(50090-4493) | | |

Revised: 4/2021 A-S Medication Solutions