DRAMAMINE - N- meclizine hydrochloride tablet Medtech Products 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.

Dramamine-N Nausea

Drug Facts

Active ingredient (in each tablet)

Meclizine HCl 25 mg

Purpose

Antiemetic

Use

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

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble 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 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 doctor before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- take first dose one hour before activity that may result in nausea
- adults and children 12 years and over: 1 to 2 tablets once daily, or as directed by a doctor

Other information

■ store at room temperature 20°–25°C (68°-77°F)

Inactive ingredients

anhydrous lactose, corn starch, colloidal silicon dioxide, D&C yellow no. 10 aluminum lake, magnesium stearate, microcrystalline cellulose

Questions?

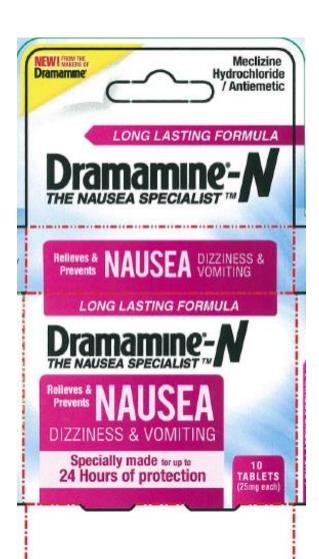
1-800-382-7219 Dramamine.com

PRINCIPAL DISPLAY PANEL

Dramamine®-N

Meclizine Hydrochloride Tablets/Antiemetic

10 Tablets





meclizine hydrochloride tablet

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63029-905 |
| 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

| Inactive Ingredients | | |
|-------------------------------------------------|----------|--|
| Ingredient Name | Strength | |
| ANHYDROUS LACTOSE (UNII: 3S Y5LH9 PMK) | | |
| STARCH, CORN (UNII: O8232NY3SJ) | | |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) | | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | |
| MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U) | | |

| Product Characteristics | | | |
|-------------------------|--------|--------------|----------|
| Color | YELLOW | Score | 2 pieces |
| Shape | ROUND | Size | 9 mm |
| Flavor | | Imprint Code | |
| Contains | | | |

| Packaging | | | |
|--------------------|--------------------------------------------------------|-----------------------------|---------------------------|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:63029-905-10 | 2 in 1 BOX | 0 1/15/20 18 | |
| 1 | 5 in 1 BLISTER PACK; 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 | 0 1/15/20 18 | |
| | | | |

Labeler - Medtech Products Inc. (122715688)

Revised: 2/2019 Medtech Products Inc.