

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 HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	YELLOW	Score	2 pieces
Shape	ROUND	Size	9mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-905-10	2 in 1 BOX	01/15/2018	
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	01/15/2018	

Labeler - Medtech Products Inc. (122715688)