MECLIZINE HYDROCHLORIDE- meclizine hydrochloride tablet APNAR PHARMA LP

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.

Meclizine Hydrochloride Tablets 25 mg

Active ingredient (in each 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 in 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

- 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

- to prevent motion sickness, take the first dose one hour before starting activity
- not for frequent or prolonged use except on the advice of a doctor
- do not exceed recommended dose

Adults and children 12 years of age and older: Take 1-2 tablets once daily, or as directed by a doctor. Do not exceed 2 tablets in 24 hours.

Other information

- store at room temperature 15°-30°C (59°-86°F)
- protect from humidity

Inactive ingredients: D&C yellow # 10 lake, lactose monohydrate, magnesium stearate, microcrystalline cellulose, colloidal silicon dioxide.

Questions or Comments?

Call 1-855-642-2594

Tamper evident:Do not use if safety seal is broken or missing

Comapre to active ingredient in DRAMAMINE ® ALL DAY LESS DROWSY*

*This product is not manufactured or distributed by the owner of registered trademark of DRAMAMINE $^{\circledR}$

MADE IN USA

Manufactured by:

APNAR PHARMA LLP

East Windsor, NJ 08520

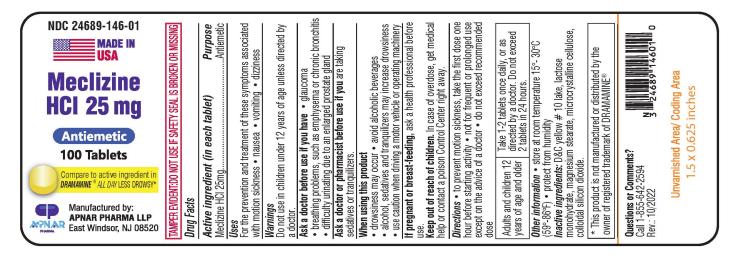
Rev.:10/2022

NDC 24689-146-01

Meclizine HCL 25 mg

Antiemetic

100 Tablets



MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:24689-146 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII: 3L5TQ84570)	MECLIZ INE HYDROCHLORIDE	25 mg	

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		

Product Characteristics			
Color	yellow	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	AM4
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:24689-146- 01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2022		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	M009	11/21/2022		

Labeler - APNAR PHARMA LP (079568229)

Establishment			
Name	Address	ID/FEI	Business Operations
APNAR PHARMA LLP		118530917	manufacture(24689-146), analysis(24689-146), pack(24689-146)

Revised: 11/2022 APNAR PHARMA LP