

**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

Compare to active ingredient in DRAMAMINE<sup>®</sup> ALL DAY LESS DROWSY\*

\*This product is not manufactured or distributed by the owner of registered trademark of DRAMAMINE<sup>®</sup>

### 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

<b>NDC 24689-146-01</b>	
	
<b>Meclizine HCl 25 mg</b>	
<b>Antiemetic</b>	
<b>100 Tablets</b>	
Compare to active ingredient in DRAMAMINE <sup>®</sup> ALL DAY LESS DROWSY*	
Manufactured by: <b>APNAR PHARMA LLP</b> East Windsor, NJ 08520	
<b>TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING</b>	
<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient (in each tablet)</b> Meclizine HCl, 25mg.....Antiemetic	
<b>Uses</b> For the prevention and treatment of these symptoms associated with motion sickness • nausea • vomiting • dizziness	
<b>Warnings</b> Do not use in children under 12 years of age unless directed by a doctor.	
<b>Ask a doctor before use if you have</b> • glaucoma • breathing problems, such as emphysema or chronic bronchitis • difficulty urinating due to an enlarged prostate gland	
<b>Ask a doctor or pharmacist before use if you are taking</b> sedatives or tranquilizers.	
<b>When using this product</b> • drowsiness may occur • avoid alcoholic beverages • alcohol, sedatives and tranquilizers may increase drowsiness • use caution when driving a motor vehicle or operating machinery	
<b>If pregnant or breast-feeding</b> , ask a health professional before use.	
<b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a poison Control Center right away.	
<b>Directions</b> • 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.
<b>Other information</b> • store at room temperature 15°- 30°C (59°-86°F) • protect from humidity	
<b>Inactive ingredients:</b> D&C yellow # 10 lake, lactose monohydrate, magnesium stearate, microcrystalline cellulose, colloidal silicon dioxide.	
* This product is not manufactured or distributed by the owner of registered trademark of DRAMAMINE <sup>®</sup>	
<b>Questions or Comments?</b> Call 1-855-642-2594 Rev.: 10/2022	 N 24689-14601 0
<b>Unvarnished Area/ Coding Area</b> 1.5 x 0.625 inches	

## MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:24689-146
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	25 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
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**

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	AM4
<b>Contains</b>			

**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**

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

**Labeler** - APNAR PHARMA LP (079568229)**Establishment**

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