

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

Active Ingredient (in each tablet)

12.5mg tablet: Meclizine HCL.... 12.5 mg

25mg tablet : Meclizine HCL25 mg

Purpose

Antiemetic

Uses

Prevents and treats nausea, vomiting or dizziness associated with motion sickness

Directions

Meclizine HCL 12.5mg tablet :

Dosage should be taken one hour before travel starts -adults & children 12 years and over: take 2 or 4 tablets once daily or as directed by a doctor

Meclizine HCL 25mg tablet:

Dosage should be taken one hour before travel starts -adults & children 12 years and over: take 1 or 2 tablets once daily or as directed by a doctor

Inactive Ingredients

Magnesium stearate, microcrystalline cellulose, silicon dioxide, lactose monohydrate

Other Information:

store at 20° to 25°C (68° to 77°F), excursions permitted between 15° to 30°C (59° to 86°F) [see USP controlled room temperature]

Do not use in children under 12 years of age unless directed by a doctor

Do not take this product, unless directed by a doctor, if you have

- Glaucoma
- A breathing problem such as emphysema or chronic bronchitis
- Trouble urination due to an enlarged prostate gland

Do not take this product if you are taking

Sedatives or tranquilizers, without first consulting your doctor.

When using this product,

- Do not exceed recommended dosage
- may cause drowsiness

- alcohol, sedatives and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- 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 (1-800-222-1222)

Questions or Comments?

Call 1-855-642-2594

Rev.: 05/2022

Made in USA

Manufactured by:

APNAR PHARMA LLP

East Windsor, NJ 08520

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING


NDC : 24689-138-01

Mecizine Hydrochloride Tablets 12.5 mg

Antiemetic

100 Tablets

NDC 24689-138-01

 **MADE IN USA**

Mecizine HCl 12.5 mg

Antiemetic

100 Tablets



Manufactured by:
APNAR PHARMA LLP
East Windsor, NJ 08520

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING

Drug Facts

Active Ingredient (in each tablet) Purpose
Mecizine HCl 12.5 mg..... Antiemetic

Uses prevents and treats nausea, vomiting or dizziness associated with motion sickness

Directions

• dosage should be taken one hour before travel starts	adults and children take 2 or 4 tablets once daily
12 years and over	or as directed by a doctor

Inactive Ingredients magnesium stearate, microcrystalline cellulose, silicon dioxide, lactose monohydrate

Other Information Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Warnings

Do not use in children under 12 years of age unless directed by a doctor.

Do not take this product, unless directed by a doctor, if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor.


When using this product

- do not exceed recommended dosage
- may cause drowsiness
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- 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.
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Questions or Comments?
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Rev.: 05/2022



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Unvarnished Area/ Coding Area
(1.5 x 0.4 inches)

NDC : 24689-139-01

Mecizine Hydrochloride Tablets 25 mg

Antiemetic

100 Tablets



**Meclizine
HCl 25 mg**

Antiemetic

100 Tablets

NDC 24689-139-01

**MADE IN
USA**

Drug Facts

Active Ingredient (in each tablet) Purpose
Meclizine HCl 25 mg..... Antiemetic

Uses prevents and treats nausea, vomiting or dizziness associated with motion sickness

Directions

- dosage should be taken one hour before travel starts

adults and children take 1 or 2 tablets once daily
12 years and over or as directed by a doctor

Inactive Ingredients magnesium stearate, microcrystalline cellulose, silicon dioxide, lactose monohydrate

Other Information Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Warnings

Do not use in children under 12 years of age unless directed by a doctor.

Do not take this product, unless directed by a doctor, if you have • glaucoma • a breathing problem such as emphysema or chronic bronchitis • trouble urinating due to an enlarged prostate gland


Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor.

When using this product • do not exceed recommended dosage • may cause drowsiness • alcohol, sedatives, and tranquilizers may increase drowsiness • avoid alcoholic drinks • use caution when driving a motor vehicle or operating machinery

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

Questions or Comments?
Call 1-855-642-2594
Rev.: 05/2022



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Unvarnished Area/ Coding Area
(1.5 x 0.4 inches)

MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24689-138
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44C1O) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	12.5 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	white	Score	2 pieces
Shape	ROUND	Size	7mm
Flavor		Imprint Code	A;C4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:24689-138-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/29/2022	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	M009		07/29/2022	

MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	
Route of Administration		ORAL	NDC:24689-139	
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
Product Characteristics				
Color	white (White to off white)		Score	no score
Shape	ROUND		Size	9mm
Flavor			Imprint Code	AM7
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24689-139-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/29/2022	
Marketing Information				

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M009	07/29/2022	

Labeler - APNAR PHARMA LP (079568229)

Establishment

Name	Address	ID/FEI	Business Operations
APNAR PHARMA LLP		118530917	manufacture(24689-138, 24689-139) , analysis(24689-138, 24689-139) , pack(24689-138, 24689-139)

Establishment

Name	Address	ID/FEI	Business Operations
INVAHEALTH INC		116840615	label(24689-138, 24689-139) , pack(24689-138, 24689-139)

Revised: 7/2022

APNAR PHARMA LP