

MECLIZINE HCL 25 MG- meclizine hydrochloride tablet, chewable
Gemini Pharmaceuticals, Inc. dba Plus Pharma

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 HCl 25 mg Chewable Tablets

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each chewable tablet)

Meclizine HCl, USP 25 mg

Purpose

Antiemetic

Uses

prevents and treats nausea, vomiting or dizziness due to motion sickness

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
- a breathing problem such as emphysema or chronic bronchitis
- 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

- 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 the poison control center immediately.

Directions

- dosage should be taken one hour before travel starts.
- **adults and children 12 years of age and older:** Chew 1-2 tablets once daily or as directed by a doctor
- **children under 12 years:** do not give this product to children under 12 years of age unless directed by a doctor

Other information

- phenylketonurics: contains phenylalanine 0.28 mg per tablet
- store at room temperature in a dry place

Inactive ingredients Aspartame, croscarmellose sodium, dextrose, FD&C red #40 lake, magnesium stearate, maltodextrin, microcrystalline cellulose, natural and artificial flavors, silicon dioxide, sodium

sulfate, sugar, tricalcium phosphate.

Questions? If you have any questions or comments or to report an adverse event, please contact **(800) 795-9775**.

Distributed by: Plus Pharma, Commack, NY 11725

*Plus Pharma is not affiliated with the owner of the registered trademark Bonine®.

NDC 51645-994-01

Plus Pharma®

MECLIZINE HCl 25 mg

ANTIEMETIC



Treats and Prevents Motion Sickness

*Compare to the Active Ingredient in Bonine®

Prevents nausea, dizziness and vomiting

Raspberry

100 CHEWABLE TABLETS • 25 mg each

<p>NDC 51645-994-01</p> <p>PlusPHARMA™</p> <p>MECLIZINE HCl</p> <p>ANTIEMETIC 25 mg</p> <p>Treats and Prevents Motion Sickness</p> <p>Prevents nausea, dizziness and vomiting</p> <p>Compare to the Active Ingredient in Bonine®</p> <p>Raspberry </p> <p>100 CHEWABLE TABLETS • 25 mg each</p>	<p>Drug Facts</p> <p>Active ingredient (in each chewable tablet) Purpose Meclizine HCl, USP 25 mg.....Antiemetic</p> <p>Uses prevents and treats nausea, vomiting or dizziness due to motion sickness</p>	<p>Warnings</p> <p>Do not use in children under 12 years of age unless directed by a doctor.</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none">• a breathing problem such as emphysema or chronic bronchitis• glaucoma• trouble urinating due to an enlarged prostate gland <p>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.</p>	<p>When using this product</p> <ul style="list-style-type: none">• may cause drowsiness• alcohol, sedatives, and tranquilizers may increase drowsiness• avoid alcoholic drinks• use caution when driving a motor vehicle or operating machinery	<p>Rev. 09/15</p> <p>DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING</p> <p>*Plus Pharma is not affiliated with the owner of the registered trademark Bonine®.</p> <p> 51645994019</p> <p>3 51645994019</p> <p>Lot# Exp.</p> <p>PEEL HERE</p>	
<p>Distributed by: Plus Pharma, Commack, NY 11725</p>	<p>Questions or comments?</p> <p>If you have any questions or comments or to report an adverse event, please contact (800) 795-9775.</p>	<p>Inactive ingredients</p> <p>aspartame, croscarmellose sodium, dextrose, FD&C Red #40 Lake, magnesium stearate, maltodextrin, microcrystalline cellulose, natural and artificial flavors, silicon dioxide, sodium sulfate, sugar, tricalcium phosphate.</p>	<p>Other information</p> <ul style="list-style-type: none">• Phenylethanamines: Contains Phenylethanamine 0.28 mg per tablet• store at room temperature	<p>Directions</p> <ul style="list-style-type: none">• Dosage should be taken one hour before travel starts• Adults and children 12 years of age and older: Chew 1-2 tablets once daily, or as directed by a doctor• Children under 12 years: do not give this product to children under 12 years of age unless directed by a doctor	<p>Drug Facts (continued)</p> <p>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 the poison control center immediately.</p>

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

Plus Pharma®

NDC 51645-994-10

MECLIZINE HCl 25 mg

ANTIEMETIC

Treats and Prevents Motion Sickness

Prevents nausea, dizziness and vomiting

*Compare to the Active Ingredient in Bonine®

Raspberry Natural & Artificial Flavor

Contains no ingredient from a gluten-containing grain (wheat, barley, or rye).

1000 CHEWABLE TABLETS • 25 mg each

Drug Facts

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Active ingredient (in each chewable tablet) Purpose
Meclizine HCl, USP 25 mg..... Antiemetic

Uses prevents and treats nausea, vomiting or dizziness due to motion sickness

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Lot No.:
Exp. Date: |

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NDC 51645-994-10

PlusPHARMA™

MECLIZINE HCl
ANTIEMETIC 25 mg

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**Compare to the Active Ingredient in Bonine®*

Drug Facts (continued)

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Other information
• phenyletonurics: contains phenylalanine 0.28 mg per tablet
• store at room temperature in a dry place

Inactive ingredients
Aspartame, croscarmellose sodium, dextrose, FD&C red #40 lake, magnesium stearate, maltodextrin, microcrystalline cellulose, natural and artificial flavors, silicon dioxide, sodium sulfate, sugar, tricalcium phosphate.

Questions?
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3 51645 99410 1 Rev. 09/19

MECLIZINE HCL 25 MG

meclizine hydrochloride tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51645-994
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
ASPARTAME (UNII: Z0H242BBR1)	
SUCROSE (UNII: C151H8M554)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DEXTROSE (UNII: IY9XDZ35W2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	

Product Characteristics

Color	pink (Uncoated)	Score	2 pieces
Shape	ROUND (Biconvex)	Size	8 mm
Flavor	RASPBERRY	Imprint Code	21G
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51645-994-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/15/2015	
2	NDC:51645-994-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/15/2015	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part336	10/15/20 15	
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Labeler - Gemini Pharmaceuticals, Inc. dba Plus Pharma (055942270)

Establishment

Name	Address	ID/FEI	Business Operations
Gemini Pharmaceuticals, Inc.		055942270	manufacture(51645-994)

Revised: 12/2019

Gemini Pharmaceuticals, Inc. dba Plus Pharma