# MECLIZINE HCL 25 MG- meclizine hydrochloride tablet, chewable Unit Dose Services

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.

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### Meclizine HCI 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

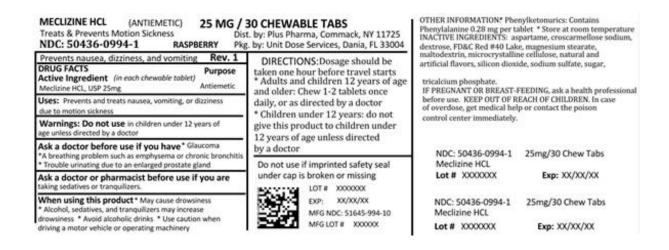
\*Plus Pharma is not affiliated with the owner of the registered trademark Bonine®.

#### **HOW SUPPLIED**

Product: 50436-0994

NDC: 50436-0994-1 30 TABLET, CHEWABLE in a BOTTLE

### MECLIZINE HCL 25 MG (MECLIZINE HYDROCHLORIDE) TABLET, CHEWABLE



### **MECLIZINE HCL 25 MG**

meclizine hydrochloride tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50436-0994(NDC:51645-994)
Route of Administration	ORAL		

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

Inactive Ingredients			
Ingredient Name	Strength		
ASPARTAME (UNII: Z0H242BBR1)			
SUCROSE (UNII: C151H8M554)			
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
MICROCRYSTALLINE CELLULOSE (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	8mm
Flavor	RASPBERRY	Imprint Code	21G
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50436- 0994-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	



Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	10/15/2015	

## Labeler - Unit Dose Services (831995316)

Establishment				
Name	Address	ID/FEI	Business Operations	
Unit Dose Services		831995316	REPACK(50436-0994), RELABEL(50436-0994)	

Revised: 9/2021 Unit Dose Services