BONINE- meclizine hydrochloride tablet, chewable Insight Pharmaceuticals

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.

BONINE® MECLIZINE HYDROCHLORIDE • ANTIEMETIC

Drug Facts

Active ingredient (in each tablet)

Meclizine HCl 25 mg

Purpose

Antiemetic

Uses

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

Warnings

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

Do not take unless directed by a doctor if you have

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

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

When using this product

- do not exceed recommended dosage
- drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful 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

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

Other information

store at room temperature 20° – 25°C (68° –77°F)

Inactive ingredients

Croscarmellose Sodium, Crospovidone, FD&C Red #40 Lake, Lactose, Magnesium Stearate, Raspberry Flavor, Silica, Sodium Saccharin, Stearic Acid, Vanilla Flavor.

Questions?

call 1-800-344-7239 or visit us on the web at www.insightpharma.com

Dist. by: INSIGHT Pharmaceuticals Corp.

Langhorne, PA 19047-1749

PRINCIPAL DISPLAY PANEL - 8 Tablet Carton

BONINE_®

MECLIZINE HYDROCHLORIDE • ANTIEMETIC

Prevents Motion Sickness

Chewable Once-A-Day Protection

8 Tablets



BONINE

meclizine hydrochloride tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-124
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
meclizine hydrochloride (UNII: HDP7W44CIO) (meclizine - UNII:3L5TQ84570)	meclizine	25 mg	

Inactive Ingredients			
Ingredient Name	Strength		
crospovidone (UNII: 68401960MK)			
FD&C Red No. 40 (UNII: WZB9127XOA)			
Aluminum Oxide (UNII: LMI26O6933)			
Lactose (UNII: J2B2A4N98G)			
Magnesium Stearate (UNII: 70097M6I30)			
Silicon Dioxide (UNII: ETJ7Z6XBU4)			
Saccharin Sodium (UNII: SB8ZUX40TY)			
stearic acid (UNII: 4ELV7Z65AP)			
Croscarmellose Sodium (UNII: M28OL1HH48)			

Product Characteristics			
Color	PINK (light pink)	Score	2 pieces
Shape	ROUND	Size	9 mm
Flavor	RASPBERRY, VANILLA	Imprint Code	Bonine;201
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-124-08	8 in 1 BOX		
2	NDC:63736-124-12	12 in 1 BOX		
3	NDC:63736-124-16	16 in 1 BOX		
4	NDC:63736-124-21	21 in 1 BOX		
5	NDC:63736-124-95	2 in 1 POUCH		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part336	06/08/2009		

Labeler - Insight Pharmaceuticals (176792315)

Revised: 1/2010 Insight Pharmaceuticals