BONINE KIDS- chlorcyclizine 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.

CHEWABLE TRAVEL TABLET BONINE® FOR KIDS

ATTENTION: USE ONLY IF TABLET BLISTER SEALS ARE UNBROKEN.

Questions? Call 1-800-344-7239

www.insightpharma.com

Distr. by: INSIGHT Pharmaceuticals Corp.

Langhorne, PA 19047-1749

*DRAMAMINE is a registered trademark of McNEIL-PPC, Inc.

Drug Facts

Active ingredient (in each tablet)	Purpose
Cyclizine HCl 25 mg	
Antiemetic	

Uses

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

Warnings

Do not use in children under 6 years of age unless directed by a doctor

Do not take or give to children if they have a breathing problem such as chronic bronchitis or glaucoma without first consulting a doctor

Do not take or give to children if they are taking sedatives or tranquilizers without first consulting a doctor

When using this product

- do not exceed recommended dosage
- drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- children 6 years of age and older: chew 1 tablet thoroughly every 6 to 8 hours
- do not exceed 3 tablets in 24 hours or as directed by a doctor
- dosage should be taken up to one hour before travel starts or at onset of symptoms

Other information

• store at room temperature $20^{\circ}-25^{\circ}$ C ($86^{\circ}-77^{\circ}$ F)

Inactive ingredients

Croscarmellose Sodium, Ethylcellulose, D&C Red #27 Lake, FD&C Blue #2 Lake, Hydroxypropylcellulose, Hypromellose, Magnesium Stearate, Mannitol, N&A Flavors, Sorbitol, Sucralose

PRINCIPAL DISPLAY PANEL - Box of 8 Tablets

CHEWABLE TRAVEL TABLET BONINE $_{\mathbb{R}}$

CYCLIZINE HYDROCHLORIDE • ANTIEMETIC

FOR KIDS

The Product to Use at the Onset of Symptoms

Berry Blast

8 Chewable Tablets



BONUS 50% MORE12 TABLETS FOR THE PRICE OF 8 TABLETS

CHEWABLE TRAVEL TABLET BONINE $_{\circledR}$

CYCLIZINE HYDROCHLORIDE • ANTIEMETIC

FOR KIDS

The Product to Use at the Onset of Symptoms

Berry Blast

12 Chewable Tablets



68240B

CAUSES LESS DROWSINESS THAN ORIGINAL DRAMAMINE.*

BONUS 50% MORE

12 TABLETS FOR THE PRICE OF 8 TABLETS



CYCLIZINE HYDROCHLORIDE . ANTIEMETIC



Barry Blast 12 8 Chewable Tablets 36"00

Inactive Ingredients Croscam ellose Sodium, Bhytoellulose, D&C Red & 7 Lake, FD &C Blue # 2 Lake, Hydroxyp ropybellulose, Hypromellose, Magneslum Stearab, Manntfol, M& A Flavors, Sorbitol, Sucralose

Other information • store at no on temperature 20° 2° 3° 7° F)

Drug Facts (continued)

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When using this product

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Do not take or give to children if they have a breathing problem such as chronic

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Drug Facts



chlorcyclizine hydrochloride tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-044
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Chlorcyclizine Hydrochloride (UNII: NPB7A7874U) (Chlorcyclizine - UNII:M26C4IP44P)	Chlorcyclizine	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)				
vanilla (UNII: Q74T35078H)				
Tamma (et.a. Q. 11556, et.a)				

Product Characteristics			
Color	PINK	Score	2 pieces
Shape	ROUND	Size	14mm
Flavor	BERRY	Imprint Code	Bonine
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63736-044-08	8 in 1 BOX			
2	NDC:63736-044-12	12 in 1 BOX			

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: 6/2009 Insight Pharmaceuticals