SEA-CALM- meclizine hcl 25mg chewable tablets tablet, chewable
Bellegrove

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.

Drug Facts

Active ingredient

Meclizine Hydrochloride 25 mg

Purpose

Antiemetic

Uses

For the prevention and treatment of nausea, vomiting or dizziness associated with motion sickness

Warnings

Do not take this product if you have asthma, glaucoma, emphysema, chronic pulmonary disease, shortness of breath, difficulty in breathing, or difficulty in urination due to enlargement of the prostate gland, unless directed by a physician. Do not give to children under 12 years of age unless directed by a physician. May cause drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your physician. Use caution when driving a motor vehicle or operating machinery. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

Directions

Adult oral dosage is one to two tablets once daily or as directed by a physician.

Inactive ingredients

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

Package/Label Principal Display Panel

SEA-CALM

meclizine hcl 25mg chewable tablets tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59961-123
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
LACTOSE (UNII: J2B2A4N98G)	
CROSPOVIDONE (UNII: 68401960MK)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
RASPBERRY (UNII: 4N14V5R27W)	
VANILLA (UNII: Q74T35078H)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	PINK	**Score**	2 pieces
Shape	ROUND	**Size**	9mm
Flavor	FRUIT	**Imprint Code**	BMS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59961-123-01	2 in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	03/16/2009	

Labeler - Bellegrove (070966486)

Registrant - Contract Pharmacal Corporation (057795122)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corporation		057795122	MANUFACTURE

Revised: 3/2010 Bellegrove