TRAVEL SICKNESS MECLIZINE HCL- meclizine hcl 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.

TRAVEL SICKNESS MECLIZINE HCL

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 it 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
- Keep lid tightly closed

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 or comments?

call **1-800-645-2158**

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

Distributed by: Rugby Laboratories

17177 N. Laurel Park Drive, Suite 233, Livonia, MI 48152

HOW SUPPLIED

Product: 50436-3989

NDC: 50436-3989-1 30 TABLET, CHEWABLE in a BOTTLE

RUGBY TRAVEL SICKNESS MECLIZINE HCL, 25 MG EACH (ANTIEMETIC) (MECLIZINE HCL) TABLET, CHEWABLE

TRAVEL SICKNESS MECLIZINE HCL meclizine hcl tablet, chewable			
Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50436-3989(NDC:0536-1018)
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
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)	
SUCROSE (UNII: C151H8M554)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50436-3989-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	08/19/2014	

Labeler - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-3989)

Revised: 9/2017 Unit Dose Services