

**RUGBY TRAVEL SICKNESS MECLIZINE HCL, 25 MG EACH (ANTIEMETIC)- meclizine hcl tablet, chewable**

**Aphena Pharma Solutions - Tennessee, LLC**

*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 CHEWABLE TABLETS**

***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
- 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

**Repackaging Information**

Please reference the **How Supplied** section listed above for a description of individual tablets. This drug product has been received by Aphenia Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphenia are listed below:

<b>Count</b>	<b>25 mg</b>
30	71610-245-30
90	71610-245-60

Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:



Cookeville, TN 38506

20190314JH

**PRINCIPAL DISPLAY PANEL - 25 mg**

NDC 71610-245 - Meclizine HCl (Travel Sickness) 25 mg Chewable Tablets



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

meclizine hcl tablet, chewable

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:716 10 -245(NDC:0536 -10 18)
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 (UNII: IY9XDZ35W2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (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:71610-245-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/28/2019	
2	NDC:71610-245-60	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/28/2019	

**Marketing Information**

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

**Labeler** - Aphenia Pharma Solutions - Tennessee, LLC (128385585)**Establishment**

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-245)

Revised: 3/2019

Aphenia Pharma Solutions - Tennessee, LLC