

**MECLIZINE HYDROCHLORIDE- meclizine hydrochloride 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.*

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**5172C- Rubgy**

**Drug Facts**

**Active ingredient (in each chewable tablet)**

Meclizine HCl 25 mg

**Purpose**

Antiemetic

**Uses**

prevents and treats nausea, vomiting or dizziness due to motion sickness

**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**

- Do not exceed recommended dosage
- 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 a Poison Control Center right away (1-800-222-1222).

## **Directions**

□ Dosage should be taken one hour before travel starts

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adults and children 12 years of age and over	chew 1 to 2 tablets once daily, or as directed by a doctor
children under 12 years of age	do not give this product to children under 12 years of age unless directed by a doctor

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## **Other information**

□ Each tablet contains 0.09 mg of Magnesium and 0.82 mg of Sodium

□ store at room temperature in a dry place

□ keep lid tightly closed

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

## **Questions or comments?**

1-800-645-2158

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

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

\*This product is not manufactured or distributed by Prestige Brands, Inc owner of the registered trademark Bonine®.

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RUGBY® LABORATORIES  
17177 N Laurel Park Dr., Suite 233  
Livonia, MI 48152  
www.rugbylaboratories.com

## **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:

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<b>Count</b>	<b>25 mg</b>
30	71610-526-30
90	71610-526-60

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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:

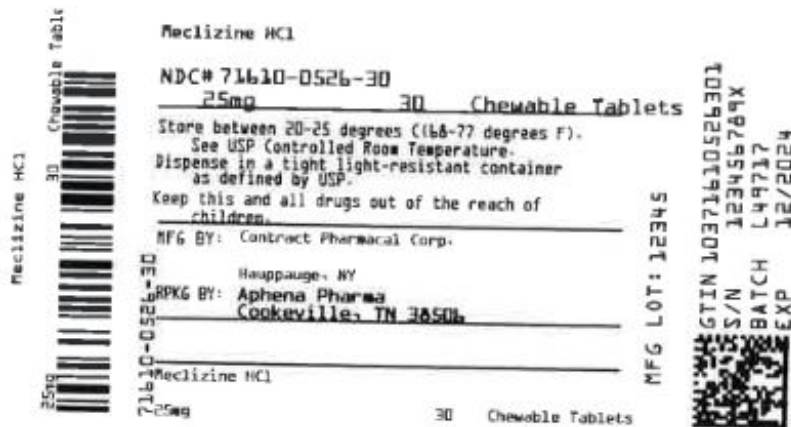


Cookeville, TN 38506

20210318JH

**PRINCIPAL DISPLAY PANEL - 25 mg**

NDC 71610-526 - Meclizine HCl 25 mg Tablets



**MECLIZINE HYDROCHLORIDE**

meclizine hydrochloride tablet, chewable

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71610-526(NDC:0536-1299)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>MECLIZINE HYDROCHLORIDE</b> (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	25 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>CROSPROVIDONE</b> (UNII: 2S7830E561)	
<b>VANILLA</b> (UNII: Q74T35078H)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>RASPBERRY</b> (UNII: 4N14V5R27W)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

## Product Characteristics

<b>Color</b>	pink (Rosy)	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	9mm
<b>Flavor</b>	VANILLA, RASPBERRY	<b>Imprint Code</b>	5172
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71610-526-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2021	
2	NDC:71610-526-60	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	10/30/2020	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-526)

Revised: 3/2021

Aphenia Pharma Solutions - Tennessee, LLC