MECLIZINE HYDROCHLORIDE- meclizine hydrochloride tablet, chewable
Aphena Pharma Solutions - Tennessee, LLC

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

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

Other information

 Store in a dry place at 15°-30°C (59°-86°F)
 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

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

*This product is not manufactured or distributed by Wellspring Pharmaceutical Corporation, owner of the registered trademark Bonine®.

Distributed by:
RUGBY® LABORATORIES
Indianapolis, IN 46268
www.rugbylaboratories.com

REPACKAGING INFORMATION

Please reference the HOW SUPPLIED section listed above for a description of individual drug products listed below. This drug product has been received by Aphena Pharma Solutions - Tennessee, LLC in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphena are listed below:

25mg
NDC 71610-836-30, Bottles of 30 Tablets
NDC 71610-836-53, Bottles of 60 Tablets
NDC 71610-836-60, Bottles of 90 Tablets
NDC 71610-836-80, Bottles of 180 Tablets

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.

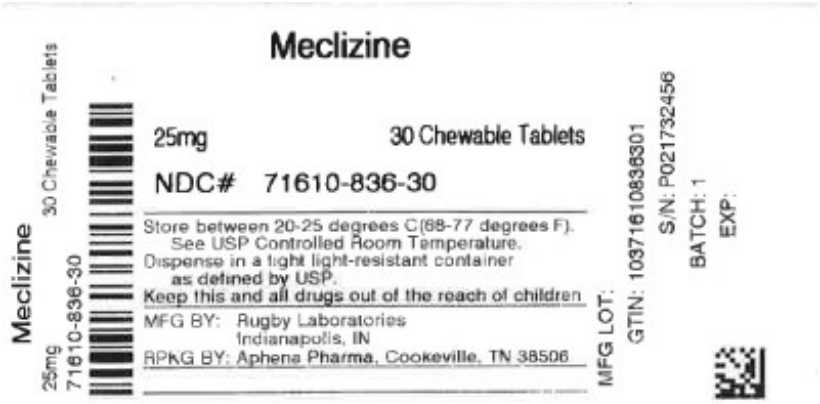
Repackaged by:

Cookeville, TN 38506

20240529AMH

PRINCIPAL DISPLAY PANEL - 25mg

NDC 71610-836 - Meclizine 25mg Tablets - Rx Only



MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71610-836(NDC:0536-1299)
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**
CROSPOVIDONE (UNII: 2S7830E561)	
VANILLA (UNII: Q74T35078H)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
RASPBERRY (UNII: 4N14V5R27W)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71610-836-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2024	
2	NDC:71610-836-53	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2024	
3	NDC:71610-836-60	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2024	
4	NDC:71610-836-80	180 in 1 BOTTLE; Type 0: Not a Combination Product	05/24/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M009	10/30/2020	

Labeler - Aphena Pharma Solutions - Tennessee, LLC (128385585)

Establishment

Name	Address	ID/FEI	Business Operations
Aphena Pharma Solutions - Tennessee, LLC		128385585	repack(71610-836)

Revised: 6/2024 Aphena Pharma Solutions - Tennessee, LLC