MECLIZINE- meclizine hydrochloride tablet, chewable
Advanced Rx LLC

Active ingredient (in each tablet)

Meclizine HCl 25 mg

Purpose

Antiemetic

Uses

prevents and treats nausea, vomiting or dizziness associated with motion sickness

Warnings

Do not use in children under 12 years of age unless directed by a doctor.

Do not take unless directed by a doctor if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Do not take this product if you aretaking sedatives or tranquilizers, without first consulting your doctor.

When using this product

- do not exceed recommended dosage
- drowsiness may occures
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful 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

- doage should be taken 1 hour before travel starts

adults and children 12 years and over	take 1 or 2 tablets once daily or as directed by doctor

Other information

- **Tamper Evident:** do not use if safety seal under cap is broken or missing
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F).

Inactive ingredients

croscarmellose sodium, dextrose, FD&C Red#40, flavor, magnesium stearate, microcrystalline cellulose, silicon dioxide, sodium saccharine, stearic acid.

Questions or comments?

call 1-800-630-8895, 8:30 am - 4.30 pm ET, Monday-Friday

NDC 80513-421-02

**Compare to the active ingredient in Bonine ®*

Meclizine HCl 25 mg

Raspberry Flavor

Antiemetic

• Motion Sickness

• Vomiting

• Nausea

200 CHEWABLE TABLETS

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

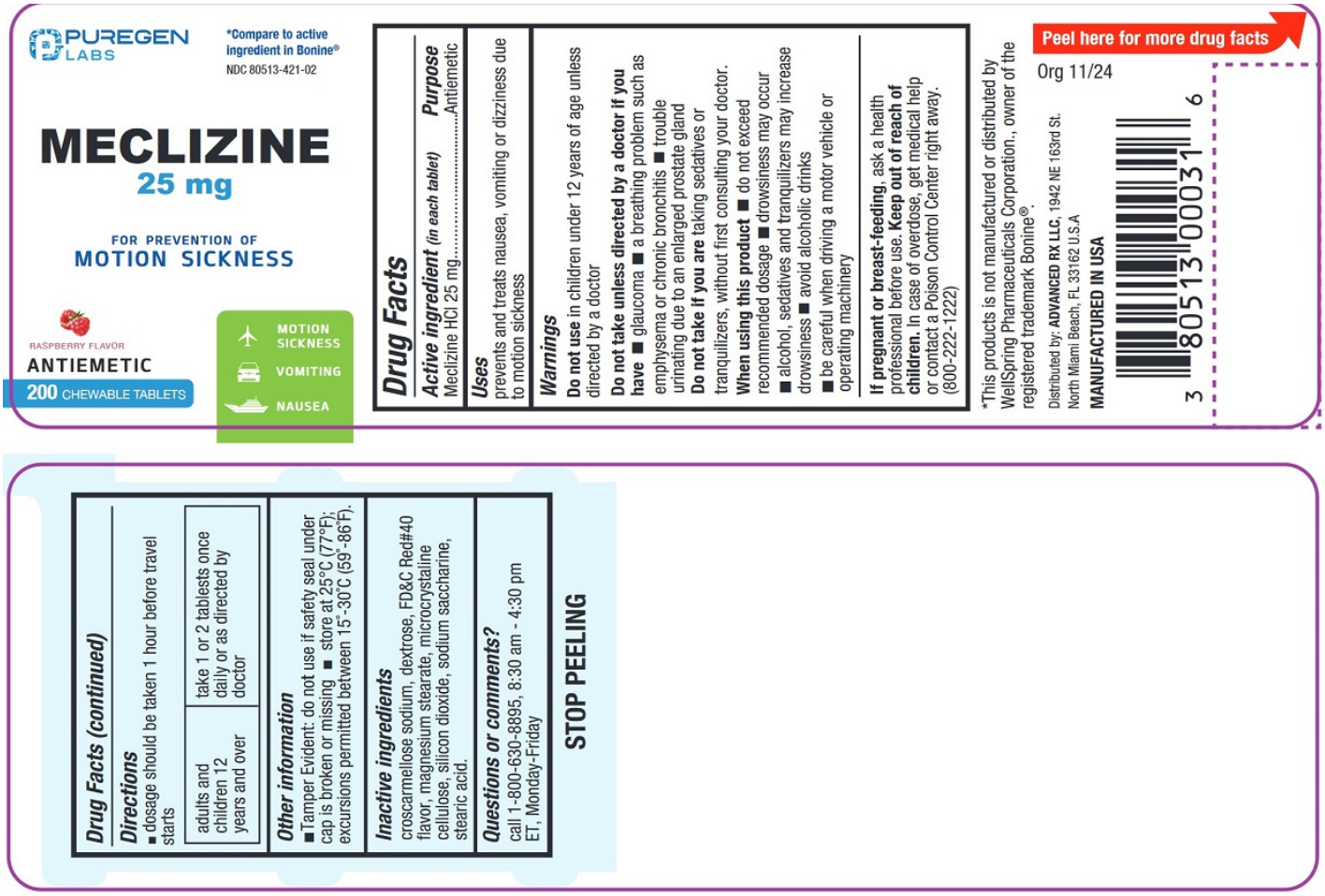
Distributed by:

ADVANCED RX LLC,

1942 NE 163rd St

North Miami Beach, FL 33162 U.S.A.

Manufactured in the USA



MECLIZINE

meclizine hydrochloride tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80513-421
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**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DEXTROSE (UNII: IY9XDZ35W2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
RASPBERRY (UNII: 4N14V5R27W)	

Product Characteristics

Color	pink (LIGHT PINK COLOR)	**Score**	2 pieces
Shape	ROUND (ROUND TABLET)	**Size**	8mm
Flavor		**Imprint Code**	PH051
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80513-421-02	200 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M009	12/01/2024	

Labeler - Advanced Rx LLC (042795108)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(80513-421) , pack(80513-421) , analysis(80513-421) , label(80513-421)

Revised: 11/2024 Advanced Rx LLC