MECLIZINE HCL- meclizine hydrochloride chewable tablet, chewable
Bryant Ranch Prepack

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.

Meclizine Hydrochloride Chewable Tablets 25 mg

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 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 0.0025 mg per tablet
- Store at room temperature in a dry place
- Keep lid tightly closed

Inactive ingredients

aspartame, colloidal silicon dioxide, croscarmellose sodium, dextrose, lake of FD & C Red 40, magnesium stearate, maltodextrin, microcrystalline cellulose, raspberry flavor, sodium sulfate anhydrous, sucrose, tribasic calcium phosphate

Questions or comments?

Call **1-844-474-7464** Monday to Friday 8 AM - 5 PM ET

TAMPER EVIDENT: DO NOT USE IF FOIL SEAL UNDER CAP, PRINTED WITH"SEALED for YOUR PROTECTION" IS BROKEN OR MISSING.
Rising Pharma Holdings, Inc. is not affiliated with the owner of the registered trademark Bonine®

Manufactured by:
Unique Pharmaceutical Laboratories
(A Div. of J.B. Chemicals & Pharmaceuticals Ltd.),
Mumbai 400 030, India

Distributed by:
Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

Mfg. Lic. No.: G/1430
Feb 2022

HOW SUPPLIED

NDC: 71335-9751-1: 30 Tablets in a BOTTLE

NDC: 71335-9751-2: 20 Tablets in a BOTTLE

NDC: 71335-9751-3: 25 Tablets in a BOTTLE

NDC: 71335-9751-4: 40 Tablets in a BOTTLE

NDC: 71335-9751-5: 60 Tablets in a BOTTLE

NDC: 71335-9751-6: 90 Tablets in a BOTTLE

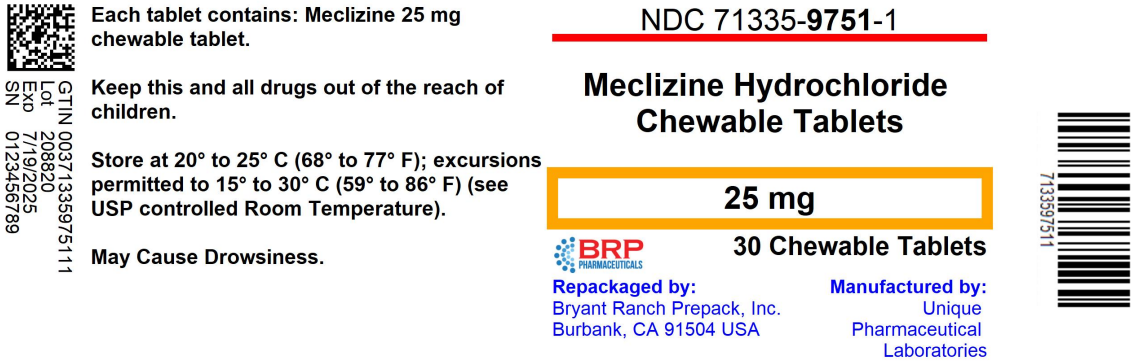
NDC: 71335-9751-7: 8 Tablets in a BOTTLE

NDC: 71335-9751-8: 14 Tablets in a BOTTLE

NDC: 71335-9751-9: 10 Tablets in a BOTTLE

NDC: 71335-9751-0: 120 Tablets in a BOTTLE

Meclizine 25 mg Chewable



MECLIZINE HCL

meclizine hydrochloride chewable tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71335-9751(NDC:16571-824)
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)	
RASPBERRY (UNII: 4N14V5R27W)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM SULFATE ANHYDROUS (UNII: 36KCS0R750)	
SUCROSE (UNII: C151H8M554)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	

Product Characteristics

Color	pink (Pink to light pink)	**Score**	2 pieces
Shape	ROUND	**Size**	8mm
Flavor	RASPBERRY	**Imprint Code**	M
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-9751-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/19/2023	
2	NDC:71335-9751-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	07/19/2023	
3	NDC:71335-9751-3	25 in 1 BOTTLE; Type 0: Not a Combination Product	07/19/2023	
4	NDC:71335-9751-4	40 in 1 BOTTLE; Type 0: Not a Combination Product	07/19/2023	
5	NDC:71335-9751-5	60 in 1 BOTTLE; Type 0: Not a Combination Product	07/19/2023	
6	NDC:71335-9751-6	90 in 1 BOTTLE; Type 0: Not a Combination Product	07/19/2023	
7	NDC:71335-9751-7	8 in 1 BOTTLE; Type 0: Not a Combination Product	07/19/2023	
8	NDC:71335-9751-8	14 in 1 BOTTLE; Type 0: Not a Combination Product	07/19/2023	
9	NDC:71335-9751-9	10 in 1 BOTTLE; Type 0: Not a Combination Product	07/19/2023	
10	NDC:71335-9751-0	120 in 1 BOTTLE; Type 0: Not a Combination Product	07/19/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	08/18/2022	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-9751) , RELABEL(71335-9751)