MOTION-TIME CHEWABLE- meclizine hcl 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.

4483-333 - MOTION TIME

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 give to children under 12 years of age unless directed by a doctor

Do not take unless directed by a doctor if you have
- trouble urinating due to an enlarged prostate gland
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis

Do not take if you are
taking sedatives or tranquilizers, without first consulting your doctor

When using this product
- do not exceed recommended dosage
- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- 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.

Directions
- dosage should be taken one hour before travel starts
- adults and children 12 years of age and over: take 1 to 2 tablets once daily or as directed by a doctor

Other information

- store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F) in a dry place
- use by expiration date on package

Inactive ingredients
anhydrous lactose, colloidal silicon dioxide, crospovidone, dextrose, FD-C red 40 aluminum lake, magnesium stearate, microcrystalline cellulose, modified corn starch, propylene glycol, raspberry flavor, silicon dioxide, sodium saccharin, stearic acid, talc, vanilla flavor

HOW SUPPLIED

Product: 71335-0821

NDC: 71335-0821-0 120 TABLET, CHEWABLE in a BOTTLE

NDC: 71335-0821-1 30 TABLET, CHEWABLE in a BOTTLE

NDC: 71335-0821-2 20 TABLET, CHEWABLE in a BOTTLE

NDC: 71335-0821-3 25 TABLET, CHEWABLE in a BOTTLE

NDC: 71335-0821-4 40 TABLET, CHEWABLE in a BOTTLE

NDC: 71335-0821-5 60 TABLET, CHEWABLE in a BOTTLE

NDC: 71335-0821-6 90 TABLET, CHEWABLE in a BOTTLE

NDC: 71335-0821-7 8 TABLET, CHEWABLE in a BOTTLE

NDC: 71335-0821-8 14 TABLET, CHEWABLE in a BOTTLE

NDC: 71335-0821-9 10 TABLET, CHEWABLE in a BOTTLE

Meclizine 25MG Chewable

MOTION-TIME CHEWABLE

meclizine hcl tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71335-0821(NDC:49483-333)

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 in 25

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
RASPBERRY (UNII: 4N14V5R27W)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
VANILLA (UNII: Q74T35078H)	

Product Characteristics

Color	pink	**Score**	2 pieces
Shape	ROUND	**Size**	9mm
Flavor	RASPBERRY	**Imprint Code**	TCL333
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-0821-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2018	
2	NDC:71335-0821-4	40 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2018	
3	NDC:71335-0821-7	8 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2018	
4	NDC:71335-0821-5	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2018	
5	NDC:71335-0821-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2018	
6	NDC:71335-0821-8	14 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2018	
7	NDC:71335-0821-3	25 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2018	
8	NDC:71335-0821-9	10 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2018	
9	NDC:71335-0821-0	120 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2018	
10	NDC:71335-0821-6	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	08/09/2010	

Labeler - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-0821) , RELABEL(71335-0821)