BONINE- meclizine hydrochloride tablet, chewable WellSpring Pharmaceutical Corporation

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.

BONINE[®] MECLIZINE HYDROCHLORIDE • ANTIEMETIC

Nausea - Dizziness - Vomiting

*Less drowsy than Dramamine

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 this product, unless directed by a doctor, if you have

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

Do not take this product if you are

taking sedatives or tranquilizers, without first consulting your doctor.

When using this product

- do not exceed recommended dosage
- you may get drowsy
- 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.

Directions (65197-275)

- 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

Directions (65197-296)

- dosage should be taken one hour before travel starts
- chew or crush tablets completely before swallowing; do not swallow tablets whole
- adults and children 12 years and over: take 1 to 2 chewable tablets once daily or as directed by a doctor

Other information

TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN

store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients (65197-275)

croscarmellose sodium, crospovidone, FD&C red #40 lake, lactose, magnesium stearate, raspberry flavor, silica, sodium saccharin, stearic acid, vanilla flavor.

Inactive Ingredients (65197-296)

corn starch, FD&C red #40 aluminum lake, flavor, lactose anhydrous, magnesium stearate, saccharin sodium, silicon dioxide

Questions?

1 (844) 241-5454 or www.bonine.com

TAMPER EVIDENT 65197-275

TAMPER EVIDENT: DO NOT USE IF TAMPER EVIDENCE TAPE OVER CAP IS BROKEN OR MISSING.

TAMPER EVIDENT 65197-296

ATTENTION: DO NOT USE IF CARTON IS OPEN OR IF BLISTER IS TORN OR MISSING.

Keep Carton for important drug facts information.

Dist. by:

WellSpring Pharmaceutical Corporation Sarasota, FL 34243 © 2023 WellSpring Pharmaceutical Corporation

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL 65197-275

UP TO 24 HOUR PROTECTION

BONINE[®] MECLIZINE HYDROCHLORIDE • ANTIEMETIC

Nausea - Dizziness - Vomiting

*Less drowsy than Dramamine



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL 65197-296

NEW LOOK! Same great formula

9X the Adventure**

**Results may vary.

Meclizine HCL • Antiemetic 25mg

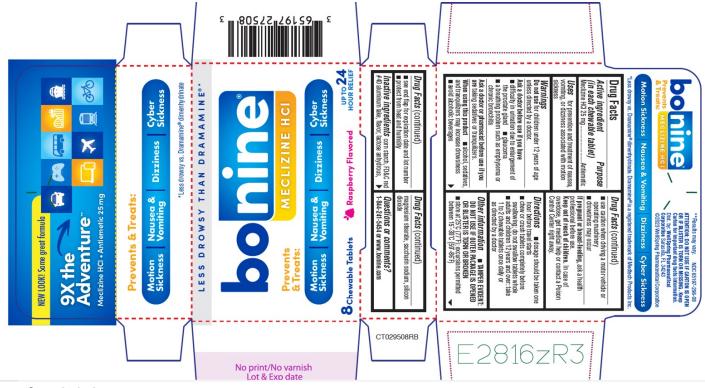
*Less drowsy than Dramamine ®

BONINE[®]

MECLIZINE HCL

Prevents & Treats: Motion Sickness / Nausea & Vomiting / Dizziness / Cyber Sickness

Up to 24 Hours Relief



Bonine 2.0 8ct

	:hewable JMAN OTC DRUG RAL	Item Code (Sc			
Product InformationProduct TypeHU	JMAN OTC DRUG	Item Code (Sc			
Product InformationProduct TypeHU	JMAN OTC DRUG	Item Code (Sc	ource)		
Product Type Hu		ltem Code (Sc	ource)		
		Item Code (So	urce)		
Route of Administration OF	RAL		Juice	NDC:6519	7-275
Active Ingredient/Active Mo	oiety				
Ingredie	ent Name		Basis of St	rength	Strength
MECLIZINE HYDROCHLORIDE (UNII: UNII:3L5TQ84570)	HDP7W44CIO) (MECLIZIN	NE -	MECLIZ INE HYDROCHLORIDE	E	25 mg
Inactive Ingredients					
Ir	ngredient Name			Stre	ength
CROSCARMELLOSE SODIUM (UNII: M	M28OL1HH48)				

CROSPOVIDONE (UNII: 2S7830E561)	
FD&C RED NO. 40 (UNII: WZ B9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
RASPBERRY (UNII: 4N14V5R27W)	
VANILLA (UNII: Q74T35078H)	

Product Characteristics

Color	pink (light pink)	Score	2 pieces
Shape	ROUND	Size	9mm
Flavor	RASPBERRY, VANILLA	Imprint Code	Bonine;201
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65197-275- 08	1 in 1 BOX	12/15/2014	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:65197-275- 12	1 in 1 BOX	12/15/2014	
2		12 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:65197-275- 16	2 in 1 BOX	12/15/2014	
3		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:65197-275- 02	2 in 1 POUCH; Type 0: Not a Combination Product	12/15/2014	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph final	part336	12/15/2014	

BONINE

meclizine hydrochloride tablet, chewable

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65197-296	
Route of Administration	ORAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Streng	th Strength
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII: 3L5TQ84570)	MECLIZ INE HYDROCHLORIDE	25 mg
Inactive Ingredients		
Ingredient Name		Strength
STARCH, CORN (UNII: 08232NY3SJ)		
FD&C RED NO. 40 (UNII: WZ B9127XOA)		
RASPBERRY (UNII: 4N14V5R27W)		

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) **MAGNESIUM STEARATE** (UNII: 70097M6I30)

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

Product Characteristics

Color	pink	Score	2 pieces
Shape	ROUND	Size	9mm
Flavor	RASPBERRY	Imprint Code	Bonine;201
Contains			

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65197-296- 08	1 in 1 BOX	02/15/2023	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:65197-296- 12	1 in 1 BOX	02/15/2023	
2		12 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:65197-296- 16	2 in 1 BOX	02/15/2023	
3		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:65197-296- 24	3 in 1 CARTON	05/01/2023	
4		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:65197-296- 32	4 in 1 CARTON	06/01/2023	
5		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
R /		Information		

Marketing Information

Marketing

Application Number or Monograph Marketing Start Marketing End

Category	Citation	Date	Date
OTC monograph final	part336	02/15/2023	

Labeler - WellSpring Pharmaceutical Corporation (110999054)

Revised: 7/2021

WellSpring Pharmaceutical Corporation