MECLIZINE HYDROCHLORIDE- meclizine hydrochloride tablet, chewable
MECLIZINE HCL- meclizine hcl tablet, chewable
DIRECTRX

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

Distributed by: Rugby Laboratories

17177 N. Laurel Park Drive, Suite 233, Livonia, MI 48152

Drug Facts

Active ingredient (in each chewable tablet)

Meclizine HCl USP 25 mg

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 it 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 of age 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 0.28 mg per tablet
Store at room temperature in a dry place
Keep lid tightly closed

aspartame, croscarmellose sodium, dextrose, FD&C Red #40 Lake, magnesium stearate, maltodextrin,

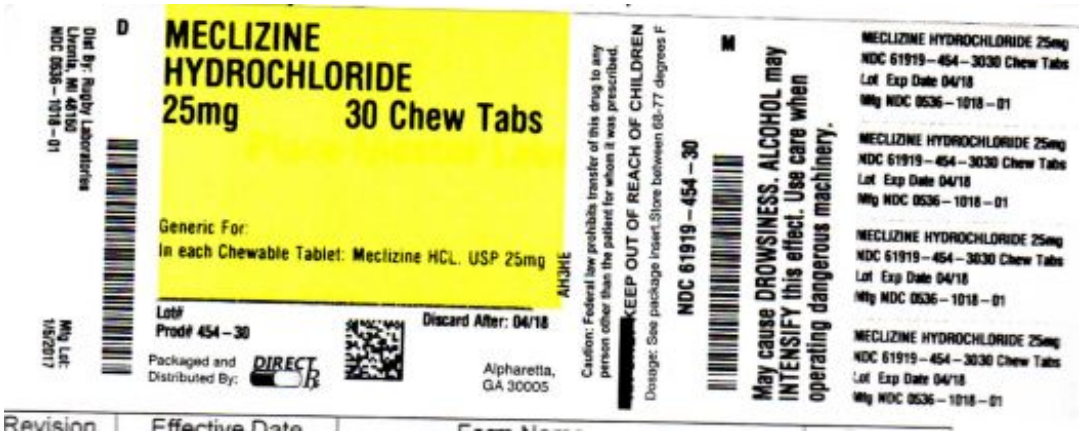
microcrystalline cellulose, natural and artificial flavors, silicon dioxide, sodium sulfate, sugar, tricalcium phosphate.

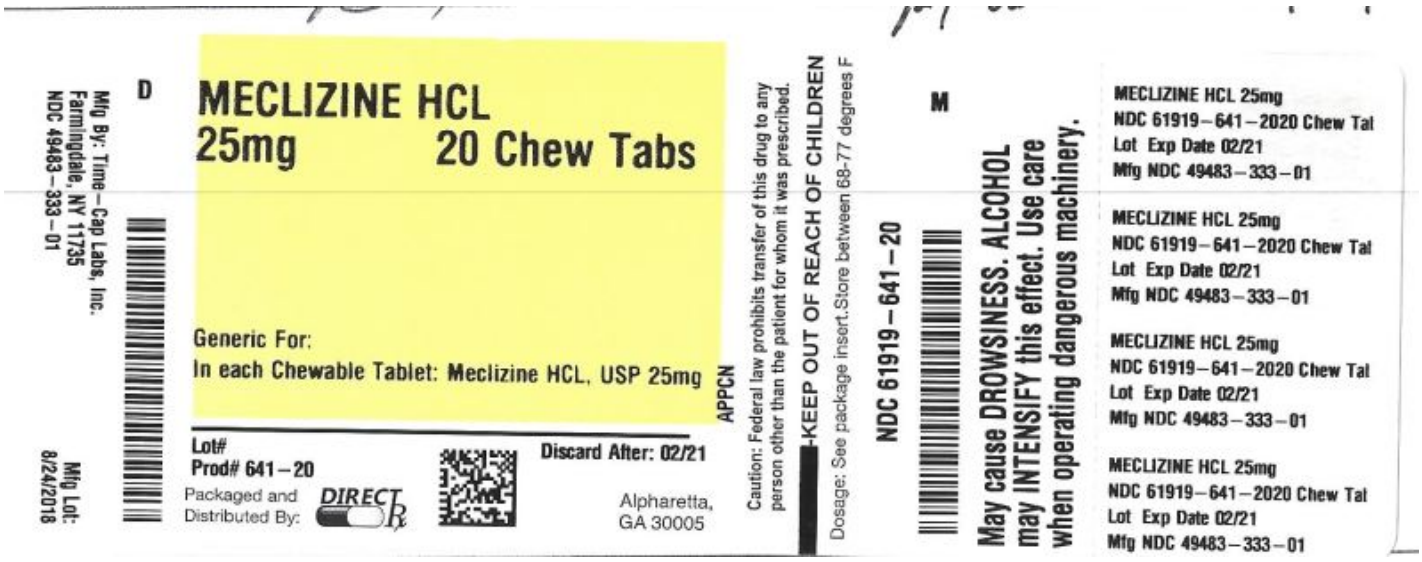
Questions or comments?

call 1-800-645-2158

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

In case of overdose, get medical help or contact a Poison Control Center right away.





MECLIZINE HYDROCHLORIDE

meclizine hydrochloride tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61919-454(NDC:0536-1018)
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)	
SUCROSE (UNII: C151H8M554)	
DEXTROSE (UNII: IY9XDZ35W2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM SULFATE (UNII: 0YPR65R21J)	

Product Characteristics			
Color	pink	**Score**	2 pieces
Shape	ROUND (Biconvex Uncoated Tablet with Bisect)	**Size**	8mm
Flavor		**Imprint Code**	21G
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61919-454-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	04/10/2019	

MECLIZINE HCL

meclizine hcl tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61919-641(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**
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
DEXTROSE (UNII: IY9XDZ35W2)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
RASPBERRY (UNII: 4N14V5R27W)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
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:61919-641-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	04/10/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	04/10/2019	

Labeler - DIRECTRX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECTRX		079254320	repack(61919-454, 61919-641)