MECLIZINE HCL 25 MG- meclizine hcl tablet
Denton Pharma, Inc. DBA Northwind Pharmaceuticals

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 HCL 25 mg

Drug Facts

Active ingredient (in each tablet)

Meclizine HCL 25 mg

Purpose

Antiemetic

Uses

- prevents and treats nausea, vomiting or dizziness due to motion sickness
- for others uses, consult your doctor

Warnings

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 prodcut

- you may get drowsy
- 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.

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
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Directions

- take dose one hour before travel starts
- tablets can be chewed or swallowed whole with water

adults & children 12 years and over: 1-2 tablets once daily

children unser 12 years: ask a doctor

Other information

- **Phenylketonurics: each tablet contrains:** phenylalanine 0.28 mg
- store at room temperature 15°-30°C (59°-86°F)
- This is a bulf package. Dispense contents with a child-resistant closure in a tight, light-resistant container as defined in the USP.

Inactive ingredients

aspartame, compressible sugar, croscarmellose sodium, dextrose, FD&C red # 40 (Al-lake), magnesium stearate, microcrystalline cellulose, raspberry flavor

Questions or comments?

call **516-341-0666,** 8:30 am - 4:30 pm ET, Monday - Friday

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

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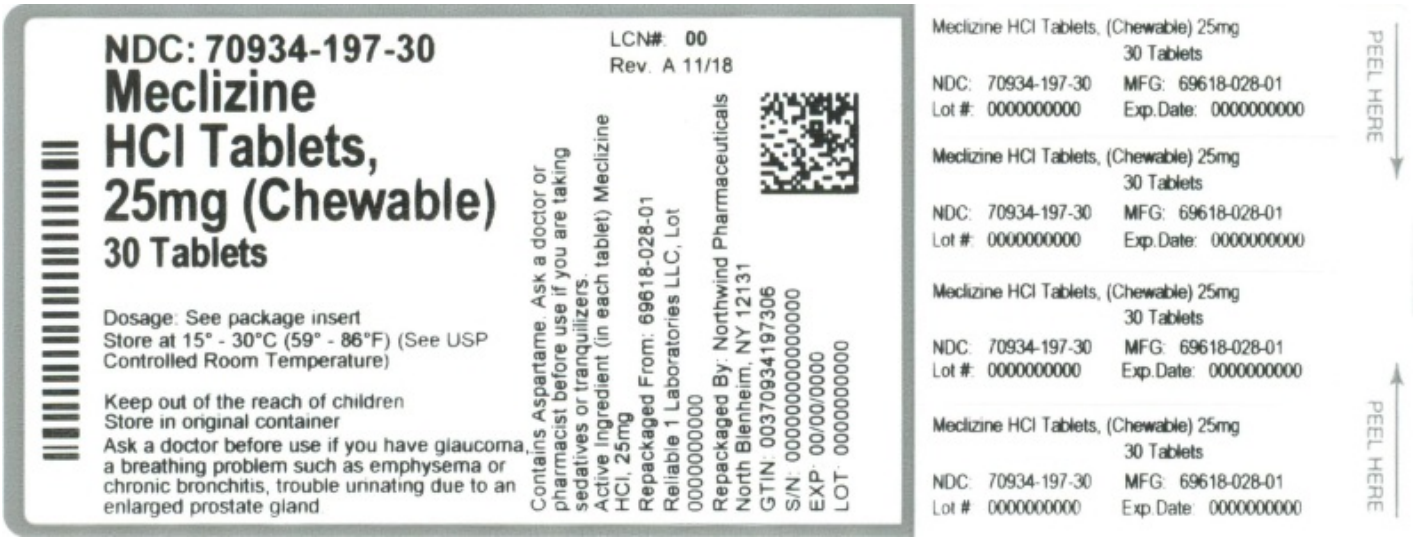
Principal Display Panel

NDC: 70934-197-30



MECLIZINE HCL 25 MG

meclizine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70934-197(NDC:69618-028)
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**
DEXTROSE (UNII: IY9XDZ35W2)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
RASPBERRY (UNII: 4N14V5R27W)	
ASPARTAME (UNII: Z0H242BBR1)	
SUCROSE (UNII: C151H8M554)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics			
Color	pink (Light Raspberry color)	**Score**	2 pieces
Shape	ROUND	**Size**	8mm
Flavor	RASPBERRY	**Imprint Code**	AP;115
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70934-197-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/05/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	12/05/2018	

Labeler - Denton Pharma, Inc. DBA Northwind Pharmaceuticals (080355546)

Registrant - Denton Pharma, Inc. DBA Northwind Pharmaceuticals (080355546)

Establishment

Name	Address	ID/FEI	Business Operations
Denton Pharma, Inc. DBA Northwind Pharmaceuticals		080355546	repack(70934-197)