CETIRIZINE HYDROCHLORIDE (ALLERGY) - cetirizine hydrochloride tablet
NorthStar Rx LLC

Cetirizine Hydrochloride Tablets USP 10 mg (ALLERGY RELIEF)

Drug Facts

Active ingredient (in each tablet)

Cetirizine hydrochloride USP 10 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

Warnings

Do not use if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing hydroxyzine.

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding:

- If breast-feeding: not recommended
- if pregnant: 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. [1-800-222-1222]

Directions

adults and children 6 years and over	one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms.
adults 65 years and over	ask a doctor
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- store between 20° to 25°C (68° to 77°F)
- **TAMPER EVIDENT: DO NOT USE IF SEAL OVER BOTTLE OPENING IS BROKEN OR MISSING**

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

Questions?

call **1-800-206-7821**

Manufactured for: Northstar Rx LLC

Memphis, TN 38141

Manufactured by: Aurobindo Pharma Limited

Hyderabad-500 090, India

Code: TS/DRUGS/19/1993

Issued: 03/2018

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg (500's Tablets Container Label)

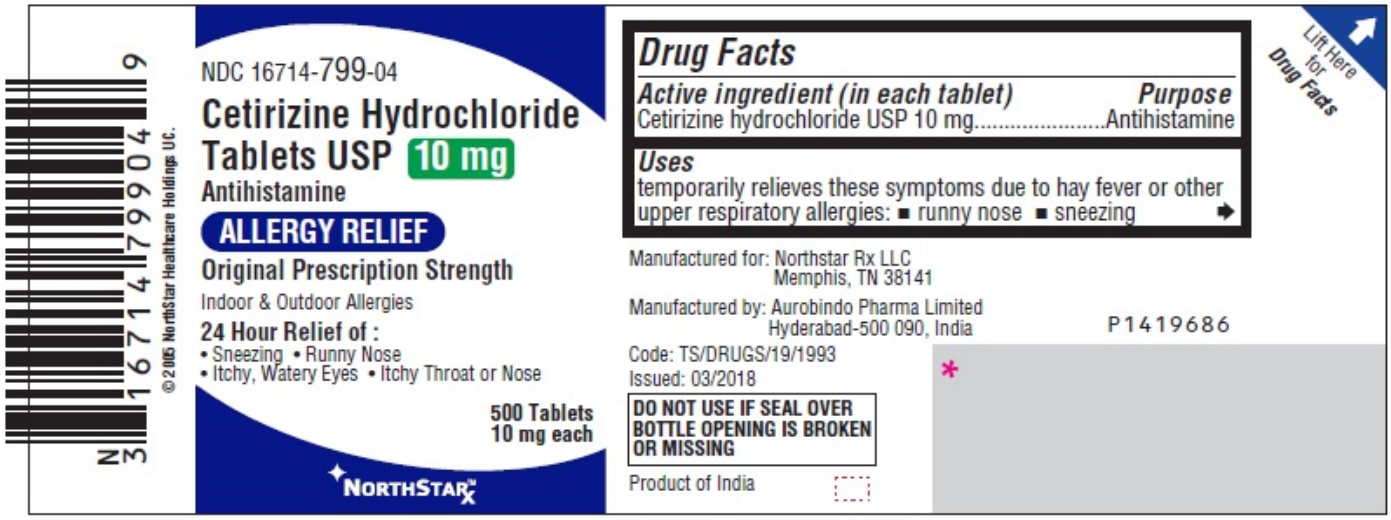
NDC 16714-799-04
Cetirizine Hydrochloride
Tablets USP 10 mg
Antihistamine
ALLERGY RELIEF
Original Prescription Strength
Indoor & Outdoor Allergies

24 Hour Relief of :

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

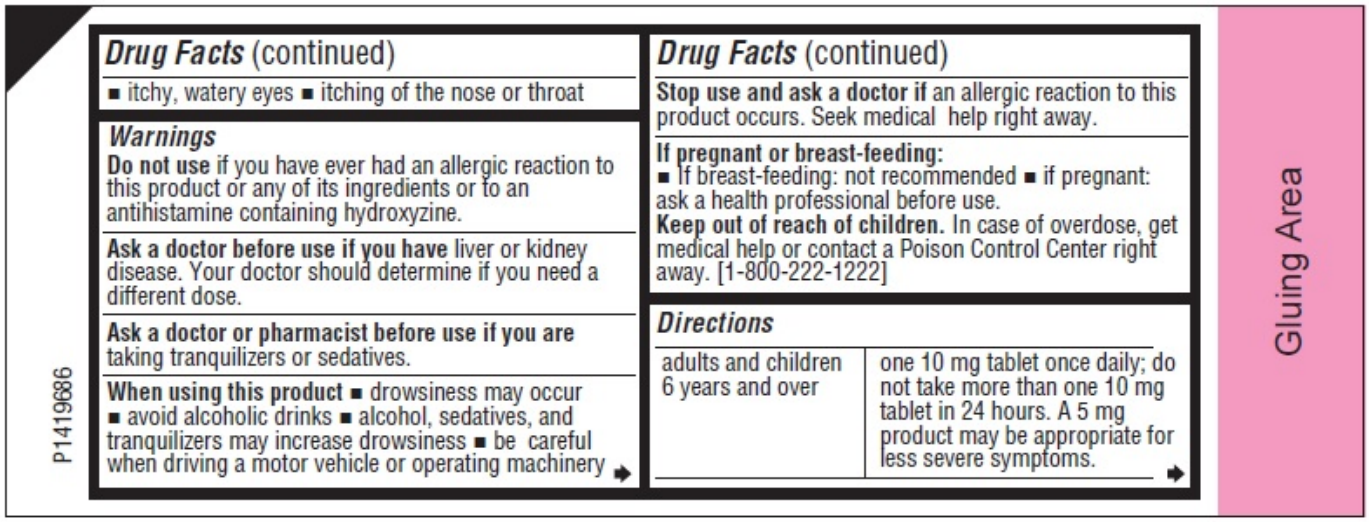
500 Tablets

10 mg each



Position for Vendor logo

* Lot: XXXXXXXXX
EXP: MM/YYYY
Prefix & Variables of Lot, EXP shall be printed online during packing.



CETIRIZINE HYDROCHLORIDE (ALLERGY)

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:16714-799
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (White to Off-white)	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	X;36
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:16714-799-01	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2015	
2	NDC:16714-799-02	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2015	
3	NDC:16714-799-03	300 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2015	
4	NDC:16714-799-04	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090760	08/05/2015	

Labeler - NorthStar Rx LLC (830546433)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(16714-799) , MANUFACTURE(16714-799)