CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
DIRECT RX

CETIRIZINE HYDROCHLORIDE

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.

Active Ingredients (in each tablet) Purpose
Cetirizine HCl 10
mg.....Antihistimine

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

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.

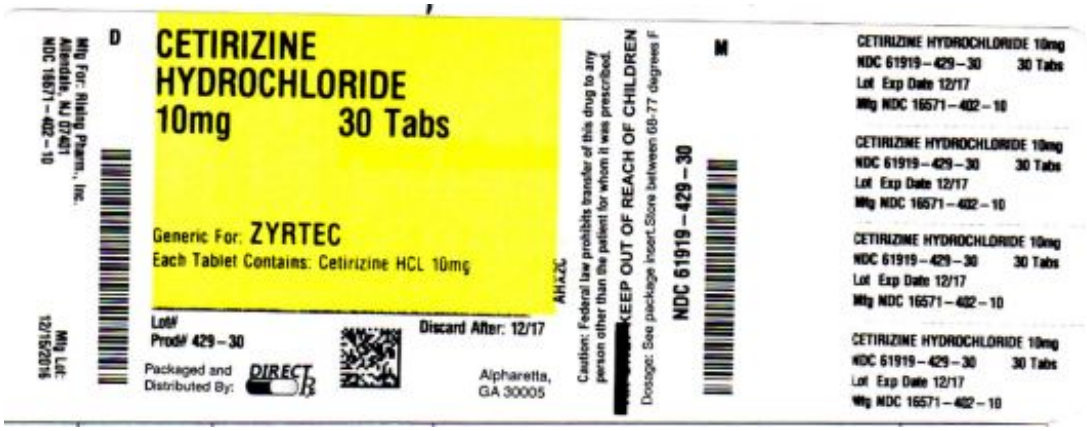
drowsines may occur
avoid alcoholic drinks
alcohol, sedatives, and tranquilizers may increase drowsiness
be careful when driving a motor vehicle or operating machinary.

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

if breast-feeding: not recommended
if pregnant: ask a health professional before use.

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

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 sever 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



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61919-429(NDC:16571-402)
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**
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	

Product Characteristics			
Color	white	**Score**	no score
Shape	BULLET	**Size**	8mm
Flavor		**Imprint Code**	CTN;10
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:61919-429-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/22/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077829	12/22/2016	

Labeler - DIRECT RX (079254320)

Registrant - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	repack(61919-429)

Revised: 1/2023 DIRECT RX