CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet, film coated
A-S Medication Solutions

Cetrizine HCL Tablet 10 mg

Drug Facts

Active ingredient (in each tablet)

Cetirizine HCl, 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.

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° and 25°C (68° - 77°F)
- USP Dissolution Test 3

Inactive ingredients

Lactose monohydrate, microcrystalline cellulose, starch (corn), magnesium stearate, hypromellose, polydextrose, polyethylene glycol and titanium dioxide.

Questions or comments?

call **1-800-706-5575**, weekdays, 8:30am - 5:00pm Eastern Standard Time

Manufactured by:	Manufactured for:
Apotex Inc.	Apotex Corp.
Toronto, Ontario	Weston, Florida
Canada M9L 1T9	33326

HOW SUPPLIED

Product: 50090-3188

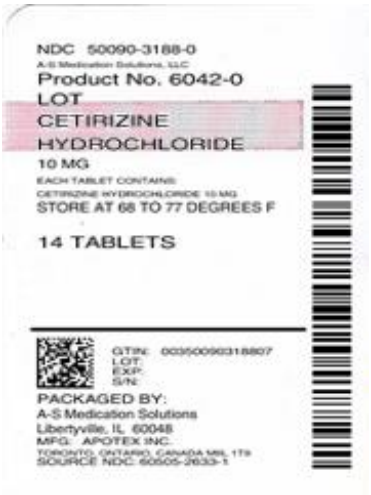
NDC: 50090-3188-0 14 TABLET, FILM COATED in a BOTTLE

NDC: 50090-3188-1 30 TABLET, FILM COATED in a BOTTLE, PLASTIC

NDC: 50090-3188-3 90 TABLET, FILM COATED in a BOTTLE, PLASTIC

NDC: 50090-3188-2 100 TABLET, FILM COATED in a BOTTLE, PLASTIC

Cetirizine Hydrochloride



CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50090-3188(NDC:60505-2633)
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**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	RECTANGLE (pillow-shaped)	**Size**	9mm
Flavor		**Imprint Code**	10MG;APO
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-3188-0	14 in 1 BOTTLE; Type 0: Not a Combination Product	10/23/2017	
2	NDC:50090-3188-1	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/28/2014	
3	NDC:50090-3188-3	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/28/2014	
4	NDC:50090-3188-2	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/28/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078317	12/27/2007	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-3188) , REPACK(50090-3188)

Revised: 4/2019 A-S Medication Solutions