

ALLERGY RELIEF- cetirizine hydrochloride tablet, coated
AAA PHARMACEUTICAL, INC.

RES - 1194A - 2019-0911

Drug Facts

Active ingredient (in each tablet)

Cetirizine HCl 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)
- retain carton for complete product information and warnings

Inactive ingredients

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

Questions or Comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

RESTORE U

24 HR

NDC 57344-194-01

COMPARE TO THE ACTIVE INGREDIENT IN ZYRTEC®

Allergy Relief

Cetirizine Hydrochloride Tablets, 10 mg / Antihistamine

Indoor and Outdoor Allergies

Original Prescription Strength

Relieves: Sneezing, Runny Nose, Itchy, Watery Eyes, Itchy Nose or Throat

actual size
14 TABLETS



ALLERGY RELIEF

cetirizine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57344-194
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:Y07261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	

Product Characteristics

Color	white (white to off white)	Score	2 pieces
Shape	RECTANGLE (rounded off rectangular)	Size	9mm
Flavor		Imprint Code	G;4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57344-194-01	1 in 1 CARTON	10/01/2018	
1		14 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:57344-194-14	1 in 1 CARTON	04/29/2022	
2		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209274	10/01/2018	

Labeler - AAA PHARMACEUTICAL, INC. (181192162)

Revised: 4/2022

AAA PHARMACEUTICAL, INC.