CETIRIZINE HYDROCHLORIDE 10 MG- cetirizine hydrochloride tablet
SDA Laboratories, Inc.

SDA LABORATORIES - CETIRIZINE HYDROCHLORIDE TABLETS - 10 MG (66424-564)

ACTIVE INGREDIENT (IN EACH TABLET)

CETIRIZINE HYDROCHLORIDE 10 MG

PURPOSE

ANTIHISTAMINE

USE

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 20º to 25ºC (68º and 77º F)

INACTIVE INGREDIENTS

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

QUESTIONS?

call toll free 1-800-687-0176
Mon – Fri 8 am to 5 pm


SDA
LABORATORIES
*Compare to the active ingredient of Zyrtec®
NDC 66424-564-05
0 66424 56405 4
Cetirizine Hydrochloride Tablets
Original Prescription Strength
10 mg
500 Tablets


SDA
LABORATORIES
*Compare to the active ingredient of Zyrtec®
NDC 66424-564-01
0 66424 56401 6
Cetirizine Hydrochloride Tablets
Original Prescription Strength
10 mg
100 Tablets

DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Drug Facts

Active ingredient (in each tablet) — Purpose

Cetirizine hydrochloride 10 mg.....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.

LIFT HERE

PEEL FOR DIRECTIONS G7032-500-101-0

Drug Facts, cont.

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 20º to 25ºC (68º and 77º F)

Inactive ingredients

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

Questions? call toll free **1-800-687-0176**

Mon – Fri 8 am to 5 pm

*This product is not manufactured or distributed by the owner of the registered trademark Zyrtec®

Distributed by:
SDA Laboratories

SDA Laboratories
Greenwich, CT 06830 USA

CETIRIZINE HYDROCHLORIDE 10 MG

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66424-564
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	**Score**	2 pieces
Shape	RECTANGLE (ROUNDED-OFF RECTANGLE)	**Size**	10mm
Flavor		**Imprint Code**	G4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66424-564-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2021	
2	NDC:66424-564-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2021	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
ANDA	ANDA209274	04/27/2021	

Labeler - SDA Laboratories, Inc. (948067889)

Revised: 1/2024 SDA Laboratories, Inc.