

**CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet, coated**  
**Safrel Pharmaceuticals, LLC**

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**Cetirizine Hydrochloride Tablets**

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***Drug Facts***

**Active Ingredient**

Cetirizine HCl 10 mg

**PURPOSE**

Antihistamine

**USE(S)**

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

**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**

liver or kidney disease. Your doctor should determine if you need a different dose.

**ASK A DOCTOR OR PHARMACIST BEFORE USE IF**

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 DOCTOR IF**

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

**PREGNANCY/BREASTFEEDING**

- 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

**STORAGE**

- store between 20° to 25°C (68° to 77°F)

**Other information**

☐Contains no ingredient made from a gluten-containing grain (wheat, barley or rye).

**Inactive ingredients**

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

**PRINCIPAL DISPLAY PANEL**

\*Compare to Zyrtec® active ingredient

NDC 71309-005-03

**Safrel®**  
**All Day Allergy**  
 indoor & outdoor allergies

Cetirizine Hydrochloride Caplets  
 Antihistamine

**10 mg**

24 hour relief of:  
 • sneezing  
 • runny nose  
 • itchy, watery eyes  
 • itchy throat or nose

**300 Caplets**

**Drug Facts**  
**Active ingredient (in each tablet)**  
 Cetirizine HCl 10 mg.....Antihistamine

**Purpose**  
 temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:  
 ■ runny nose ■ itchy, watery eyes  
 ■ sneezing ■ itchy nose or throat

**Uses**  
 temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:  
 ■ runny nose ■ itchy, watery eyes  
 ■ sneezing ■ itchy 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 your doctor or pharmacist before use if you are taking tranquilizers or sedatives.**

**When using this product**  
 ■ drowsiness may occur  
 ■ avoid alcoholic beverages

**DRUG FACTS CONTINUED on back of the label**

**DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING**

Distributed By: Safrel Pharmaceuticals  
 Bridgewater, NJ 08807 USA  
 www.safrelpharma.com

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 PEEL HERE

**STOP PEELING**

**Drug Facts (continued)**  
 ■ alcohol, sedatives, and tranquilizers may increase drowsiness  
 ■ use caution when driving a motor vehicle or operating machinery  
 ■ excitability may occur, especially in children

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

**If pregnant or breast-feeding**, 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 10mg tablet once daily.  
 Children under 6 years of age: ask a doctor  
 Consumers with liver or kidney disease: ask a doctor

**Other information**  
 store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

**Inactive ingredients**  
 lactose monohydrate, magnesium stearate, sodium starch glycolate and starch maize pregelatinized

**Questions or Comments? 1-844-364-3723**

## CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet, coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71309-005
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: EWQ57Q815X)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6130)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-005-03	300 in 1 BOTTLE; Type 0: Not a Combination Product	05/28/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209274	05/28/2018	

**Labeler** - Safrel Pharmaceuticals, LLC (080566287)

Revised: 10/2020

Safrel Pharmaceuticals, LLC