

CETIRIZINE HYDROCHLORIDE- cetirizine hydrochloride tablet
Rugby Laboratories, Inc.

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
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- 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	take 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)

Inactive Ingredients

lactose monohydrate, magnesium stearate, polyvinyl alcohol, polyethylene glycol, povidone, starch, talc, titanium dioxide.

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to Active Ingredient in ZYRTEC®*

Original Prescription Strength

ALLERGY RELIEF

CETIRIZINE HYDROCHLORIDE TABLETS, 10 mg

ANTIHISTAMINE

ALLERGY

Indoor and Outdoor Allergies

24 hour relief of:

- Runny nose
- Sneezing
- Itchy, watery eyes
- Itchy throat or nose

TABLETS

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

*Rugby Laboratories is not affiliated with the owner of the trademark Zyrtec®.

Distributed by:

Rugby Laboratories

17177 N Laurel Park Dr., Suite 233

Livonia, MI 48152

www.rugbylaboratories.com

Product Label

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

<p>Drug Facts (continued)</p> <p>Warnings</p> <p>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.</p> <p>Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.</p> <p>Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ drowsiness may occur ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ avoid alcoholic drinks ■ be careful when driving a motor vehicle or operating machinery <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p> <p>If pregnant or breast-feeding:</p> <ul style="list-style-type: none"> ■ If breast-feeding: not recommended before use ■ If pregnant: ask a health professional before use <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>	
<p>Drug Facts (continued)</p> <p>Directions</p> <p>adults and children 6 years and over</p> <p>Take 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.</p> <p>adults 65 years and over</p> <p>ask a doctor</p> <p>children under 6 years</p> <p>ask a doctor</p> <p>of age</p> <p>ask a doctor</p> <p>consumers with liver or kidney disease</p> <p>ask a doctor</p>	
<p>Other information</p> <ul style="list-style-type: none"> ■ store between 20° to 25°C (68° to 77°F) 	
<p>Inactive ingredients</p> <p>lactose monohydrate, magnesium stearate, polyethylene glycol, polyvinyl alcohol, povidone, starch, talc, titanium dioxide</p>	
<p>Questions or comments? Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p>	

<p>Drug Facts</p> <p>Active ingredient</p> <p>(in each tablet) Cetirizine HCl 10 mg.....Antihistamine</p> <p>Purpose</p> <p>Antihistamine</p>	<p>Drug Facts (continued)</p> <p>Uses</p> <p>temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ itchy, watery eyes ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itching of the nose or throat</p>
--	---



COMPARE TO ACTIVE INGREDIENT IN ZYRTEC[®]

Original Prescription Strength

ALLERGY RELIEF

CETIRIZINE
HYDROCHLORIDE TABLETS, 10 mg
Antihistamine
ALLERGY

24 hour relief of:

- Runny Nose
- Sneezing

Indoor & Outdoor Allergies

- Sneezing
- Itchy, Watery Eyes
- Itchy Throat or Nose

actual size
24 hours
14 TABLETS

Lot No.:
Exp. Date:

*Rugby Laboratories is not affiliated with the owner of the trademark Zyrtec®.

Distributed by:
Rugby Laboratories
17177 N Laurel Park Dr., Suite 233
Livonia, MI 48152
www.rugbylaboratories.com

R0213C Rev. 07/16 R-58 Re-order No. 370189
FC000189



RUGBY Allergy Relief

CETIRIZINE HYDROCHLORIDE

cetirizine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-4088
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (white)	Score	no score
Shape	OVAL (oval)	Size	8mm

Flavor		Imprint Code	IP;46	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-4088-88	1 in 1 BOX	03/23/2012	
1		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0536-4088-07	2 in 1 BOX	03/23/2012	
2		30 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0536-4088-11	1 in 1 BOX	03/23/2012	
3		90 in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA078780	03/23/2012		

Labeler - Rugby Laboratories, Inc. (079246066)

Revised: 9/2016

Rugby Laboratories, Inc.