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
- 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 take one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 years and over 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 1-800-645-2158, 9am-5pm ET. Monday-Friday

Principal Display Panel

Compare to Active Ingredient in ZYRTEC®*

Original Prescription Strength

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

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

Distributed by: Rugby Laboratories 31778 Enterprise Drive Livonia, MI 48150 www.rugbylaboratories.com

Product Label

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

USE ONLY IF BLISTERS ARE INTACT. THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center it pregnant: ask a health professional before use.

■ if breast-feeding; not recommended If pregnant or breast-feeding:

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

- operating machinery
- be careful when driving a motor vehicle or drowsiness
- drowsiness may occur
 avoid alcoholic drinks
 alcohol, sedatives, and tranquilizers may increase

When using this product

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives. different dose.

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a

antihistamine containing hydroxyzine. Do not use if you have ever had an allergic reaction to this product or any of its ingredients or to an Warnings

Drug Facts (continued)

1-800-645-2158 Questions or comments?

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> store between 20° to 25°C (68° to 77°F) попетлоти төпт

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Drug Facts (continued)

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Purpose

Cetirizine HCI 10 mg

(in each tablet) Active ingredient

Drug Facts

itchy, watery eyes
 itching of the nose or throat

Buizaaus ■ ■ runny nose

USes temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

nund racts (continued)



NDC 0536-4088-07

Original Prescription Strength

HYDROCHLORIDE TABLETS, 10 MG Antihistamine

ALLERGY

Indoor & Outdoor Allergies



actual size 24 hours

HYDROCHLORIDE TABLE Antihistamine ALLERGY Ş 5

24 hour relief of:

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

30 TABLETS

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

Hugby Laboratories 31778 Enterprise Drive Livonia, MI 48150 www.rugbylaboratories.com

R0313B FC000190 Rev. 03/13 R-58 Re-order No. 370193



Rugby Cetirizine 10 mg Allergy Tablet

CETIRIZINE HYDROCHLORIDE

cetirizine tablet

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

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CETIRIZINE HYDRO CHLO RIDE (CETIRIZINE)	CETIRIZINE HYDROCHLORIDE	10 mg	

Inactive Ingredients			
Ingredient Name	Strength		
LACTO SE MONO HYDRATE			
MAGNESIUM STEARATE			
POLYVINYL ALCOHOL			
POLYETHYLENE GLYCOLS			
POVIDONES			
STARCH, CORN			
TALC			
TITANIUM DIO XIDE			

Product Characteristics			
Color	WHITE (white)	Score	no score
Shape	OVAL (oval)	Size	8 mm
Flavor		Imprint Code	IP;46
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0536-4088-11	4 in 1 BOX			
1		90 in 1 BLISTER PACK			
2	NDC:0536-4088-88	1 in 1 BOX			
2		14 in 1 BLISTER PACK			

3 NDC:0536-4088-07	2 in 1 BOX				
3	30 in 1 BLISTER PACK				
Mr. J. C T. C					
Marketing Information					
Marketing Category	Application Number or Monogra	ph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA078780		03/23/2012		

Labeler - Rugby Laboratories Inc (191427277)

Registrant - P and L Development of New York Corporation (800014821)

Revised: 4/2013 Rugby Laboratories Inc