

**RUGBY CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE-**  
**cetirizine hydrochloride, pseudoephedrine hydrochloride tablet, film coated, extended release**  
**Rugby Laboratories**

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**Rugby Laboratories Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets Drug Facts**

**Active ingredients (in each extended release tablet)**

Cetirizine HCl 5 mg

Pseudoephedrine HCl 120 mg

**Purpose**

Antihistamine

Nasal decongestant

**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
- nasal congestion
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

**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.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have**

- heart disease
- thyroid disease
- diabetes
- glaucoma
- high blood pressure

- trouble urinating due to an enlarged prostate gland
- 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**

- **do not use more than directed**
- 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.
- you get nervous, dizzy, or sleepless
- symptoms do not improve within 7 days or are accompanied by fever

**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**

- do not break or chew tablet; swallow tablet whole

adults and children 12 years and over	take 1 tablet every 12 hours; do not take more than 2 tablets in 24 hours.
adults 65 years and over	ask a doctor
children under 12 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)

- **do not use if blister unit is broken or torn**
- see side panel for lot number and expiration date
- meets USP *Dissolution Test 2*

**Inactive ingredients**

colloidal silicon dioxide, hypromellose, lactose monohydrate, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide

**Questions or comments?**

**1-800-645-2158**

**Package/Label Principal Display Panel**

Compare to Zyrtec-D® active ingredients

Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets

5 mg/120 mg

Antihistamine/Nasal Decongestant

Allergy and Congestion

Indoor and Outdoor Allergies

Actual Size

12 Hour Relief of:

Sneezing; Itchy, Watery Eyes;

Runny Nose; Itchy Throat or Nose;

Sinus Pressure; Nasal Congestion

12 Extended-Release Tablets

**Rugby**<sup>®</sup>

**Cetirizine Hydrochloride and Pseudoephedrine Hydrochloride  
Extended-Release Tablets**

**5 mg/120 mg**

**Antihistamine/Nasal Decongestant**



**Rugby**<sup>®</sup>

NDC 0536-1279-12

Compare to Zyrtec-D<sup>®</sup>  
active ingredients\*

**Cetirizine Hydrochloride  
and Pseudoephedrine Hydrochloride  
Extended-Release Tablets**

**5 mg/120 mg**

**Antihistamine/Nasal Decongestant**

**Allergy and Congestion**

**Indoor and Outdoor Allergies**

**12 Hour Relief of:**

Sneezing; Itchy, Watery Eyes;  
Runny Nose; Itchy Throat or Nose;  
Sinus Pressure; Nasal Congestion



Actual Size

**12 Extended-Release Tablets**

Distributed by:  
**RUGBY<sup>®</sup> LABORATORIES**  
17177 N Laurel Park Drive, Suite 233  
Livonia, MI 48152  
[www.rugbylaboratories.com](http://www.rugbylaboratories.com)

\*This product is not manufactured  
or distributed by Johnson &  
Johnson Consumer Inc.,  
distributor of Zyrtec-D<sup>®</sup>.

**CODE AREA**

14753 8T C2



## RUGBY CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

cetirizine hydrochloride, pseudoephedrine hydrochloride tablet, film coated, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-1279
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CETIRIZINE HYDROCHLORIDE</b> (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 mg
<b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	

<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 2165RE0K14)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10 mm
<b>Flavor</b>		<b>Imprint Code</b>	L147
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1279-12	12 in 1 CARTON	03/09/2020	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0536-1279-35	24 in 1 CARTON	03/09/2020	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210719	03/09/2020	

**Labeler** - Rugby Laboratories (079246066)

Revised: 7/2020

Rugby Laboratories