

**LEVOCETIRIZINE DIHYDROCHLORIDE- levocetirizine dihydrochloride tablet, coated**  
**RUGBY LABORATORIES**

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**Drug Facts**

**Active ingredient (in each tablet)**

Levocetirizine dihydrochloride USP, 5 mg

**Purpose**

Antihistamine

**Uses**

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

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

**Warnings**

**Do not use**

- if you have kidney disease
- if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing cetirizine

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

- ever had trouble urinating or emptying your bladder

**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**

- you have trouble urinating or emptying your bladder
- 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 65 years of age and older	<ul style="list-style-type: none"><li>ask a doctor</li></ul>
adults and children 12-64 years of age	<ul style="list-style-type: none"><li>take 1 tablet (5 mg) once daily in the evening</li><li>do not take more than 1 tablet (5 mg) in 24 hours</li><li>1/2 tablet (2.5 mg) once daily in the evening may be appropriate for less severe symptoms</li></ul>
children 6-11 years of age	<ul style="list-style-type: none"><li>take 1/2 tablet (2.5 mg) once daily in the evening</li><li>do not take more than 1/2 tablet (2.5 mg) in 24 hours</li></ul>
children under 6 years of age	<ul style="list-style-type: none"><li>do not use</li></ul>
consumers with kidney disease	<ul style="list-style-type: none"><li>do not use</li></ul>

## Other information

- store between 20° and 25°C (68° and 77°F)
- safety sealed: Bottle: do not use if carton was opened or if printed foil inner seal on bottle is torn or missing
- Blister: Do not use if seal is broken or if individual blister unit is open or torn

## Inactive ingredients

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

## Questions or comments?

Call 1-888-375-3784

## Carton Label

Rugby

NDC 0536-1144-92

Compare to Xyzal<sup>®</sup> Allergy 24HR  
active ingredient\*

Original Prescription Strength

**Levocetirizine**

**Dihydrochloride Tablets USP, 5 mg**

**Antihistamine**

ALLERGY 24 HOUR

Relief of:

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

35 TABLETS



6 7 0 5 7 0 0 9 1

**Drug Facts**

Active ingredient (in each tablet) Levocetirizine dihydrochloride USP, 5 mg...Antihistamine	Purpose	Directions
<b>Uses</b> temporarily relieves these symptoms due to hay fever or other respiratory allergies: • runny nose • sneezing • itchy, watery eyes • itching of the nose or throat	<b>Warnings</b> Do not use • if you have kidney disease • if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing cetirizine <b>Ask a doctor before use if you have</b> • ever had trouble urinating or emptying your bladder <b>When using this product</b> • drowsiness may occur • avoid alcoholic drinks • alcohol, sedatives, and tranquilizers may increase drowsiness • be careful when driving a motor vehicle or operating machinery <b>Stop use and ask a doctor if</b> • you have trouble urinating or emptying your bladder • an allergic reaction to this product occurs. Seek medical help right away. <b>If pregnant or breast-feeding:</b> • 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).	adults 65 years of age and older • ask a doctor
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<b>Inactive ingredients</b> colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide		
<b>Questions or comments?</b> Call 1-888-375-3784		
<b>Read directions and warnings before use. Keep this carton. It has important information.</b>		

\*This product is not manufactured or distributed by Chatterm, Inc. (part of the Sanofi Group), distributor of Xyzal® Allergy 24HR Tablets. Xyzal® is a registered trademark of UCB Group of companies.

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

R-145  
REV. 02/18  
Re-order No. 370575  
Made in INDIA



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**Rugby**®

NDC 0536-1144-92  
Compare to Xyzal® Allergy 24HR active ingredient\*

Original Prescription Strength  
**LEVOCETIRIZINE**  
Dihydrochloride Tablets USP, 5 mg  
Antihistamine

**ALLERGY**

Original Prescription Strength  
**LEVOCETIRIZINE**  
Dihydrochloride Tablets USP, 5 mg  
Antihistamine

**ALLERGY**

Relief of:

- Sneezing
- Itchy Nose or Throat

24

**HOUR**

- Runny Nose
- Itchy, Watery Eyes

**35 Tablets**



Actual Size

• Clinically Proven Relief in 60 Minutes  
• Clinically Proven Relief From Indoor And Outdoor Allergies  
• Clinically Proven Relief For 24 Hours



3 05361 14492 0

LOT \_\_\_\_\_

EXP \_\_\_\_\_

**Bottle Label**

Rugby

NDC 0536-1144-92

Original Prescription Strength  
**Levocetirizine**  
**Dihydrochloride Tablets USP**  
**5 mg | Antihistamine**

**ALLERGY 24 HOUR**

**35 TABLETS**

Rugby

NDC 0536-1144-92

Original Prescription Strength

**LEVOCETIRIZINE**  
Dihydrochloride Tablets USP  
5 mg | Antihistamine

ALLERGY

24HOUR

35 Tablets

**Active Ingredient (In each tablet)**

Levocetirizine dihydrochloride USP, 5 mg.....Antihistamine

**Uses** temporarily relieves these symptoms due to hay fever or other respiratory allergies: ■ runny nose ■ sneezing ■ Itchy, watery eyes ■ itching of the nose or throat **Warnings Do not use** ■ If you have kidney disease ■ If you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing cetirizine **Ask a doctor before use if you have** ■ ever had trouble urinating or emptying your bladder **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** ■ you have trouble urinating or emptying your bladder ■ 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

**Purpose**

Distributed by: Rugby Laboratories  
17177 N Laurel Park Drive, Suite 233  
Livonia, MI 48152  
Made in India  
R-145 REV. 02/18 Re-order No. 370575  
LOT / EXP 150072025

Peel Here



**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 65 years of age and older** ■ ask a doctor **adults and children 12-64 years of age** ■ take 1 tablet (5 mg) once daily in the evening ■ do not take more than 1 tablet (5 mg) in 24 hours ■ 1/2 tablet (2.5 mg) once daily in the evening may be appropriate for less severe symptoms **children 6-11 years of age** ■ take 1/2 tablet (2.5 mg) once daily in the evening ■ do not take more than 1/2 tablet (2.5 mg) in 24 hours **children under 6 years of age** ■ do not use **consumers with kidney disease** ■ do not use **Other information** ■ store between 20° and 25°C (68° and 77°F) ■ safety sealed: do not use if carton was opened or if printed foil inner seal on bottle is torn or missing **inactive ingredients** colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide **Questions or comments?** call 1-888-375-3784

Blister Carton



## LEVOCETIRIZINE DIHYDROCHLORIDE

levocetirizine dihydrochloride tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-1144(NDC:43598-735)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
levocetirizine dihydrochloride (UNII: SOD6A38AGA) (levo cetirizine - UNII:6U5EA9RT2O)	levo cetirizine dihydrochloride	5 mg

### Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	L
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1144-92	1 in 1 CARTON	04/20/2018	
1		35 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0536-1144-93	1 in 1 CARTON	04/20/2018	
2		55 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0536-1144-19	2 in 1 CARTON	07/06/2018	
3		5 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	ANDA210375	04/20/2018	

**Labeler** - RUGBY LABORATORIES (079246066)

Revised: 7/2018

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