

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

**Global Distributors, Inc**

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**Levocetirizine Dihydrochloride Tablets USP, 5 mg**

**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: 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**

**Levocetirizine Dihydrochloride Tablets, USP 5 mg carton**

Drug Facts	
Active Ingredient	Purpose
(In each tablet) Levocetirizine dihydrochloride USP, 5 mg ... Antihistamine	
<b>Uses</b> temporarily relieves these symptoms due to hay fever or other respiratory allergies: <ul style="list-style-type: none"> <li>■ runny nose</li> <li>■ sneezing</li> <li>■ itchy, watery eyes</li> <li>■ itching of the nose or throat</li> </ul>	
<b>Warnings</b> Do not use <ul style="list-style-type: none"> <li>■ if you have kidney disease</li> <li>■ if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing cetirizine</li> </ul>	
Ask a doctor before use if you have <ul style="list-style-type: none"> <li>■ ever had trouble urinating or emptying your bladder</li> </ul>	
<b>When using this product</b> <ul style="list-style-type: none"> <li>■ drowsiness may occur</li> <li>■ avoid alcoholic drinks</li> <li>■ alcohol, sedatives, and tranquilizers may increase drowsiness</li> <li>■ be careful when driving a motor vehicle or operating machinery</li> </ul>	
<b>Stop use and ask a doctor if</b> <ul style="list-style-type: none"> <li>■ you have trouble urinating or emptying your bladder</li> <li>■ an allergic reaction to this product occurs. Seek medical help right away.</li> </ul>	
If pregnant or breast-feeding: <ul style="list-style-type: none"> <li>■ if breast-feeding, not recommended</li> <li>■ if pregnant, ask a health professional before use</li> </ul>	
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).	

Drug Facts (continued)	
Directions	
adults 65 years of age and older	■ ask a doctor
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	■ do not use
consumers with kidney disease	■ do not use
<b>Other Information</b> <ul style="list-style-type: none"> <li>■ store between 20° and 25°C (68° and 77°F)</li> <li>■ safety sealed; do not use if carton was opened or if printed foil inner seal on bottle is torn or missing</li> </ul>	
<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	
Read directions and warnings before use. Keep this carton. It has important information.	

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

Distributed by:  
GLOBAL DISTRIBUTORS, INC.  
Turlock, CA 95382 USA

Made in INDIA

REV 12/20


NDC 81086-996-12

Compare to Xyzal® Allergy 24HR active ingredient\*

Original Prescription Strength

# Levocetirizine Dihydrochloride Tablets

## USP, 5 mg

### Antihistamine ALLERGY



120 Tablets



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

- Relief of:**
- Sneezing
  - Runny Nose
  - Itchy Nose or Throat
  - Itchy, Watery Eyes



# LEVOCETIRIZINE DIHYDROCHLORIDE

levocetirizine dihydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81086-996
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LEVOCETIRIZINE DIHYDROCHLORIDE (UNII: SOD6A38AGA) (LEVOCETIRIZINE - UNII: 6U5EA9RT2O)	LEVOCETIRIZINE 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: 3WJQ05DW1A)	

Product Characteristics			
Color	white	Score	2 pieces
Shape	OVAL	Size	9mm
Flavor		Imprint Code	L

**Contains****Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81086-996-12	1 in 1 CARTON	12/01/2020	
1		120 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	ANDA210375	12/01/2020	

**Labeler** - Global Distributors, Inc (791184070)**Registrant** - GERI-CARE PHARMACEUTICAL CORP (611196254)

Revised: 12/2021

Global Distributors, Inc