

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

**Dr. Reddy's Laboratories 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)
- (bottles only) safety sealed: do not use if carton was opened or if printed foil inner seal on bottle is torn or missing
- (blister only) safety sealed: 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**



## Bottle Label

<p>HealthCare  Aisle<sup>®</sup> NDC 43598-810-80</p> <p><b>Original Prescription Strength</b></p> <p><b>Allergy Relief</b></p> <p>Levocetirizine Dihydrochloride Tablets USP, 5 mg</p> <p>ANTI-HISTAMINE</p> <p><b>80 Tablets</b></p>	<p><b>Active ingredient (in each tablet) Purpose</b> Levocetirizine dihydrochloride USP, 5 mg.....Antihistamine</p> <p><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</p> <p><b>Warnings Do not use</b> ■ 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</p> <p><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</p> <p><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.</p>
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(Continued On Back Of Label)

Distributed by:  
**Dr. Reddy's Laboratories, Inc.**  
Princeton, NJ 08540  
REV 02/25

Made in India

150150032

LOT  
EXP

**PEEL HERE**

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 ■ 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 and comments?** call 1-888-375-3784

# LEVOCETIRIZINE DIHYDROCHLORIDE

levocetirizine dihydrochloride tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43598-810(NDC:43598-735)
<b>Route of Administration</b>	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: 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:43598-810-80	1 in 1 CARTON	12/26/2018	
1		80 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:43598-810-76	2 in 1 CARTON	12/26/2018	
2		80 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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ANDA	ANDA210375	12/26/2018	
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**Labeler -** Dr. Reddy's Laboratories Inc. (802315887)

**Establishment**

Name	Address	ID/FEI	Business Operations
Dr.Reddy's Laboratories Limited-FTO 3		918608162	analysis(43598-810) , manufacture(43598-810)

**Establishment**

Name	Address	ID/FEI	Business Operations
Reed-Lane, Inc.		001819879	repack(43598-810)

Revised: 1/2026

Dr. Reddy's Laboratories Inc.