

**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**

Revised: 10/2022

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

**Dr. Reddy's**

NDC 43598-735-35

Original Prescription Strength

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

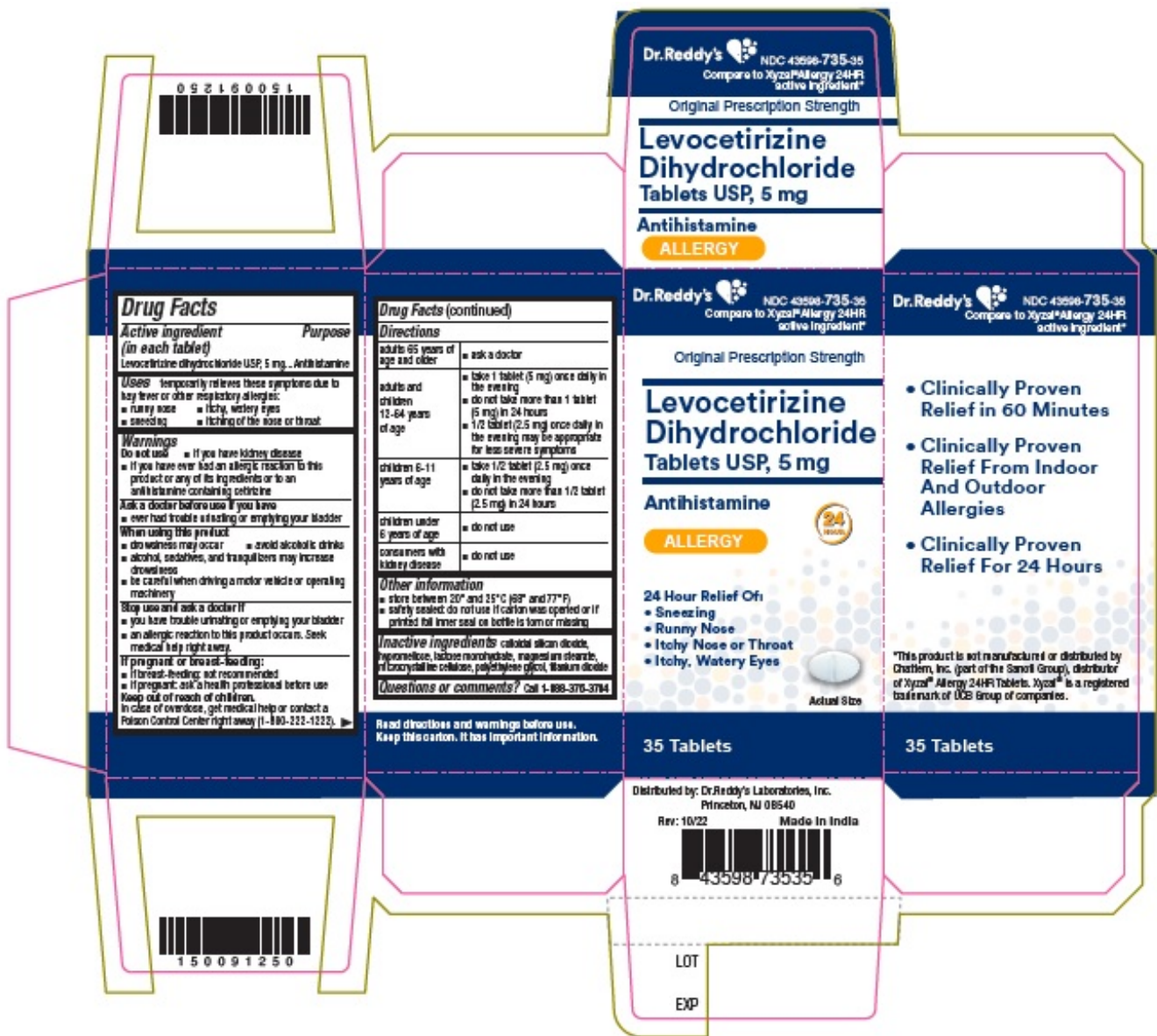
ALLERGY

24 HOUR

Relief of:

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

**35 Tablets**



## Levocetirizine Dihydrochloride Tablets USP, 5 mg bottle label

**NDC 43598-735-35**

**Dr.Reddy's**

Original Prescription Strength

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

ALLERGY

24 HOUR

**35 Tablets**

**Dr.Reddy's**  NDC 43598-735-35

Original Prescription Strength

**Levocetirizine Dihydrochloride Tablets USP, 5 mg**

Antihistamine  
**ALLERGY**

35 Tablets

**Active ingredient (in each tablet)** Purpose  
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

(Continued On Back Of Label)

Distributed by:  
Dr.Reddy's Laboratories, Inc.  
Princeton, NJ 08540  
Made in India

REV 10/2022

150072309

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:43598-735
<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:43598-735-35	1 in 1 CARTON	03/12/2018	
1		35 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:43598-735-22	1 in 1 CARTON	03/12/2018	
2		55 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:43598-735-80	1 in 1 CARTON	03/12/2018	
3		80 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:43598-735-79	2 in 1 CARTON	04/17/2018	
4		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:43598-735-04	1 in 1 CARTON	02/15/2020	
5		120 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:43598-735-95	2 in 1 CARTON	10/27/2023	
6		200 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	03/12/2018	

**Labeler** - Dr. Reddy's Laboratories Inc. (802315887)

## Establishment

Name	Address	ID/FEI	Business Operations
Dr.Reddy's Laboratories Limited-FTO 3		918608162	analysis(43598-735) , manufacture(43598-735)

## Establishment

Name	Address	ID/FEI	Business Operations
Reed-Lane, Inc.		001819879	pack(43598-735)

