# LEVOCETIRIZINE DIHYDROCHLORIDE- levocetirizine dihydrochloride tablet, coated

**Walgreens Company** 

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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-feding: 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	<ul> <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> <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

#### 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**

ORIGINAL PRESCRIPTION STRENGTH

## Compare to Xyzal® Allergy 24HR active ingredient<sup>‡‡</sup>

0363-5529-35

NEW Well at Walgreens WALGREENS PHARMACIST RECOMMENDED<sup>‡</sup>

ORIGINAL PRESCRIPTION STRENGTH

## Levocetirizine 24-Hour Allergy

## Levocetirizine Dihydrochloride Tablets, 5 mg / Antihistamine

#### Relief of:

- Sneezing
- Runny nose
- Itchy nose or throat
- Itchy, watery eyes

#### 24 HOUR

#### 35 TABLETS



#### **Bottle Label**

Well at Walgreens

NDC 0363-5529-35

ORIGINAL PRESCRIPTION STRENGTH

Levocetirizine 24-Hour Allergy

Levocetirizine Dihydrochloride Tablets, 5 mg / Antihistamine

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 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

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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 at 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

#### LEVOCETIRIZINE DIHYDROCHLORIDE

levocetirizine dihydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	

**Route of Administration ORAL**  NDC:0363-5529(NDC:43598-735)

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>levocetirizine dihydrochloride</b> (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				
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:0363-5529- 35	1 in 1 CARTON	03/26/2018			
1		35 in 1 BOTTLE; Type 0: Not a Combination Product				
2	NDC:0363-5529- 55	1 in 1 CARTON	03/26/2018			
2		55 in 1 BOTTLE; Type 0: Not a Combination Product				
3	NDC:0363-5529- 10	2 in 1 CARTON	04/17/2018			
3		5 in 1 BLISTER PACK; Type 0: Not a Combination Product				
4	NDC:0363-5529- 80	1 in 1 CARTON	03/26/2018			
4		80 in 1 BOTTLE; Type 0: Not a Combination Product				
5	NDC:0363-5529- 12	1 in 1 CARTON	01/15/2021			
5		120 in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing Information					
Marketing	Application Number or Monograph	Marketing Start	Marketing End		

Category	Citation	Date	Date
ANDA	ANDA210375	03/26/2018	

## **Labeler -** Walgreens Company (008965063)

Revised: 7/2020 Walgreens Company