

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

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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)
- (bottle only) safety sealed: do not use if carton was opened or if printed foil inner seal on bottle is torn or missing
- (blisters 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

CVS Health

Compare to the active ingredient  
in Xyzal® Allergy 24HR\*

Original Prescription Strength  
**Allergy Relief**  
**Levocetirizine Dihydrochloride**  
**Tablets USP, 5 mg**  
**Antihistamine**

**24 HOUR**

24 Hour Relief of:

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

55 TABLETS Actual bottle size on side panel



**Bottle Label**

CVS  
Health

Original Prescription Strength  
**Allergy Relief**

Levocetirizine  
Dihydrochloride  
Tablets USP, 5 mg  
Antihistamine

55 TABLETS 24 HOUR



NDC 69842-761-55

Original Prescription Strength

Allergy Relief

LEVOCETIRIZINE  
DIHYDROCHLORIDE TABLETS  
USP, 5 mg  
Antihistamine

55 TABLETS

24  
HOUR

**Active ingredient (in each tablet)**  
Levocetirizine dihydrochloride USP, 5 mg.....Antihistamine

**Purpose**  
temporarily relieves these symptoms due to hay fever or other respiratory allergies: ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itching of the nose or throat

**Uses**  
**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)

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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

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**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			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-761(NDC:43598-735)
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)			

<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)				
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)				
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)				
<b>Polyethylene Glycol, Unspecified</b> (UNII: 3WJQ0SDW1A)				
<b>Product Characteristics</b>				
<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>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69842-761-35	1 in 1 CARTON	04/15/2018	
1		35 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69842-761-80	1 in 1 CARTON	04/15/2018	
2		80 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69842-761-10	2 in 1 CARTON	12/31/2018	
3		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:69842-761-55	1 in 1 CARTON	11/30/2022	
4		55 in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA		ANDA210375	04/15/2018	

**Labeler** - CVS PHARMACY (062312574)

Revised: 10/2023

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