

**24HR ALLERGY RELIEF- levocetirizine dihydrochloride tablet, coated  
LEADER/ Cardinal Health 110, Inc.**

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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)
- (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

LEADER

NDC 70000-0362-2

Original Prescription Strength

# 24HR Allergy Relief Levocetirizine Dihydrochloride Tablets USP, 5 mg | Antihistamine

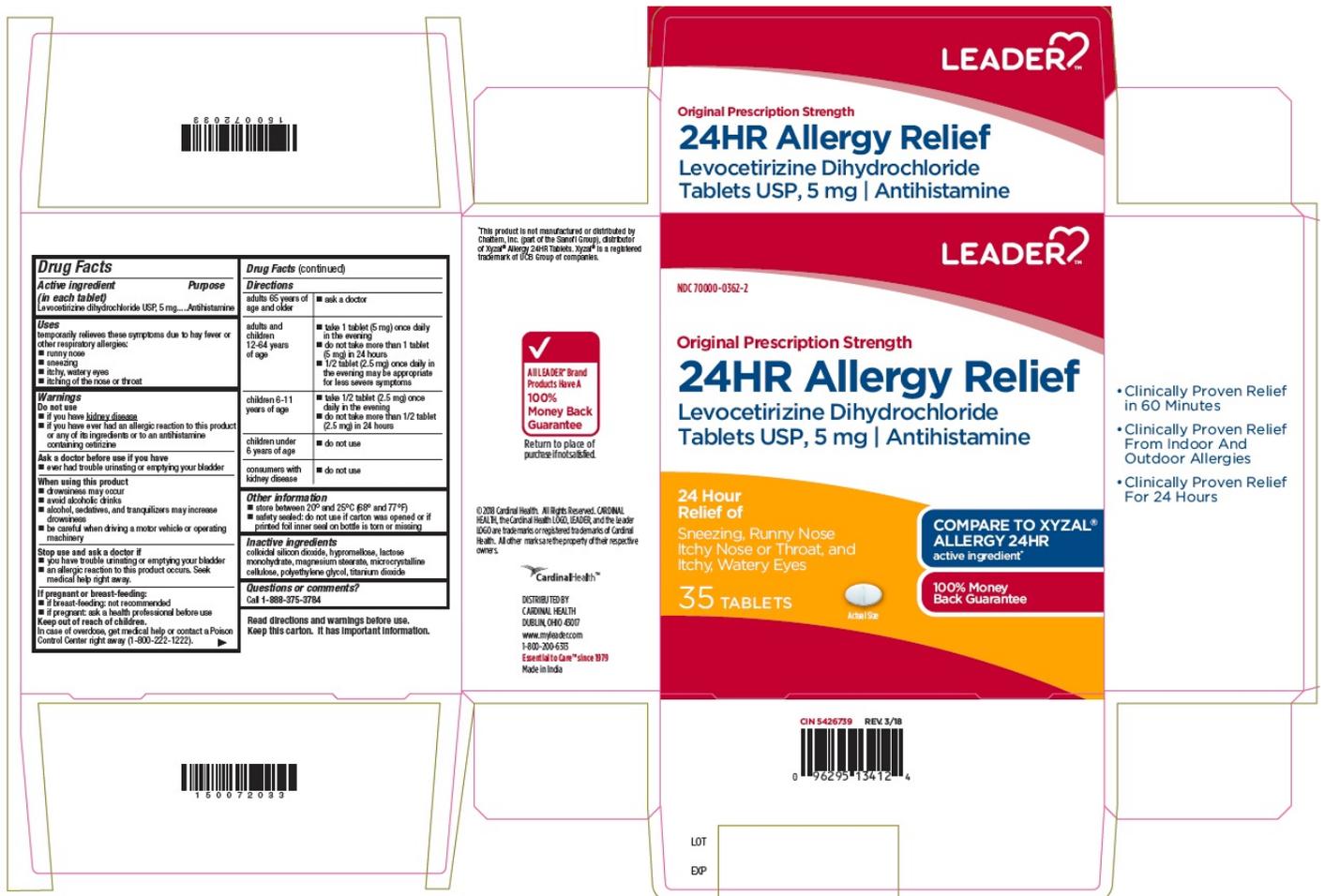
## 24 Hour Relief of

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

COMPARE TO XYZAL®  
ALLERGY 24HR  
active ingredient\*

100% Money  
Back Guarantee

**35 TABLETS**



## Bottle Label

LEADER

NDC 70000-0362-2

Original Prescription Strength

**24HR Allergy Relief**  
**Levocetirizine Dihydrochloride**  
**Tablets USP, 5 mg | Antihistamine**

**24 Hour**

**35 TABLETS**

**LEADER?**  
 NDC 70000-0362-2  
**Original Prescription Strength**  
**24HR Allergy Relief**  
**Levocetirizine Dihydrochloride Tablets USP, 5 mg | Antihistamine**  
**24 Hour**  
**35 TABLETS**

**Active Ingredient (In each tablet)**  
 Levocetirizine dihydrochloride USP, 5 mg.....Antihistamine

**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 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

**Peel Here** →

DISTRIBUTED BY  
 CARDINAL HEALTH DUBLIN, OHIO 43017  
 www.myleader.com 1-800-200-6313  
 Made In India  
 Rev. 3/18  
 LOT / EXP 150072036

**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 or comments?** call 1-888-375-3784

<b>24HR ALLERGY RELIEF</b>			
levocetirizine dihydrochloride tablet, coated			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0362(NDC:43598-735)
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
levocetirizine dihydrochloride (UNII: SOD6A38AGA) (levocetirizine - UNII:6U5EA9RT2O)		levocetirizine dihydrochloride	5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>SILICON DIOXIDE</b> (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)	

## 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:70000-0362-2	1 in 1 CARTON	03/12/2018	
1		35 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70000-0362-1	2 in 1 CARTON	08/14/2018	
2		5 in 1 BLISTER PACK; 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** - LEADER/ Cardinal Health 110, Inc. (063997360)

Revised: 10/2023

LEADER/ Cardinal Health 110, Inc.