

24HR ALLERGY RELIEF- levocetirizine dihydrochloride tablet, coated
CARDINAL HEALTH

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">ask a doctor
adults and children 12-64 years of age	<ul style="list-style-type: none">take 1 tablet (5 mg) once daily in the eveningdo not take more than 1 tablet (5 mg) in 24 hours1/2 tablet (2.5 mg) once daily in the evening may be appropriate for less severe symptoms
children 6-11 years of age	<ul style="list-style-type: none">take 1/2 tablet (2.5 mg) once daily in the eveningdo not take more than 1/2 tablet (2.5 mg) in 24 hours
children under 6 years of age	<ul style="list-style-type: none">do not use
consumers with kidney disease	<ul style="list-style-type: none">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

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

LEADER²
 NDC70000-0362-2
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
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

Purpose
 Antihistamine

Peel Here

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

24HR ALLERGY RELIEF			
levocetirizine dihydrochloride tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0362(NDC:43598-735)
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
levocetirizine dihydrochloride (UNII: SOD6A38AGA) (levo cetirizine - UNII:6U5EA9RT2O)		levo cetirizine 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: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 - CARDINAL HEALTH (097537435)

Revised: 12/2019

CARDINAL HEALTH