

LEVOCETIRIZINE DIHYDROCHLORIDE- levocetirizine dihydrochloride tablet, coated

Chain Drug Marketing Association INC

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"> • 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 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	<ul style="list-style-type: none"> • 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	<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**

Levocetirizine Dihydrochloride Tablets, USP 5 mg carton label

Original Prescription Strength

Levocetirizine Dihydrochloride Tablets USP, 5 mg Antihistamine

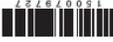
ALLERGY

24 HOUR

Relief of:

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

35 Tablets





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

Drug Facts	Purpose	Drug Facts (continued)
Active Ingredient (in each tablet) Levocetirizine dihydrochloride USP 5 mg...Antihistamine		Directions adults 65 years of age and older ask a doctor
Uses temporarily relieve these symptoms due to hay fever or other respiratory allergies: runny nose sneezing itchy, watery eyes itching of the nose or throat		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
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		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
Ask a doctor before use if you have ever had trouble urinating or emptying your bladder		children under 6 years of age do not use
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		consumers with kidney disease do not use
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.		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
if pregnant or 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).		Inactive Ingredients colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide
		Questions or comments? Call 1-888-375-3764
		Read directions and warnings before use. Keep this carton. It has important information.

NDC 63868-473-35
Compare to Xyzal® Allergy 24HR active ingredient*



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

24 HOUR ALLERGY

Relief of:

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

Actual Size 

35 Tablets



6 35515 99797 4



MADE IN INDIA

REV 02/20

LOT

EXP

- Clinically Proven Relief in 60 Minutes
- Clinically Proven Relief From Indoor And Outdoor Allergies
- Clinically Proven Relief For 24 Hours

Levocetirizine Dihydrochloride Tablets USP, 5 mg bottle label

Original Prescription Strength

Levocetirizine Dihydrochloride Tablets USP, 5 mg Antihistamine

ALLERGY

24 HOUR

35 Tablets

NDC 63868-473-35



Original Prescription Strength

Levocetirizine Dihydrochloride Tablets USP, 5 mg

Antihistamine

24 HOUR ALLERGY

35 Tablets

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

Purpose
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

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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 

REV 02/20 Made in India

Distributed by C.D.M.A., Inc.®
 43157 W 9 Mile Rd
 Novi, MI 48375
 www.qualitychoice.com
 Questions: 800-935-2362

150079724

LOT/EXP



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

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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:63868-473(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)	
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:63868-473-35	1 in 1 CARTON	06/24/2020	
1		35 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	06/24/2020	

Labeler - Chain Drug Marketing Association INC (011920774)

Establishment			
Name	Address	ID/FEI	Business Operations
Dr.Reddy's Laboratories Limited-FTO 3		918608162	analysis(63868-473) , manufacture(63868-473)

Establishment			
Name	Address	ID/FEI	Business Operations
Reed-Lane, Inc.		001819879	repack(63868-473)