LEVOCETIRIZINE DIHYDROCHLORIDE- levocetirizine dihydrochloride tablet, coated

Walmart Inc.

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	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

Carton Label



Blister Carton



LEVOCETIRIZINE DIHYDROCHLORIDE

levocetirizine dihydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-492(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				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:49035-492- 35	1 in 1 BOTTLE	07/26/2019			
1		35 in 1 BOTTLE; Type 0: Not a Combination Product				
2	NDC:49035-492- 79	2 in 1 BLISTER PACK	07/26/2019			
2		5 in 1 BLISTER PACK; Type 0: Not a Combination Product				
3	NDC:49035-492- 10	1 in 1 CARTON	01/15/2026			
3		10 in 1 BOTTLE; Type 0: Not a Combination Product				
4	NDC:49035-492- 12	1 in 1 CARTON	01/15/2026			
4		120 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	07/26/2019		

Labeler - Walmart Inc. (051957769)

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