

ALLERGY RELIEF 24HR- levocetirizine dihydrochloride tablet
Vitesse Pharma LLC

Allergy Relief 24HR

Allergy Relief 24HR Tablet

Drug Facts

Active ingredient

(in each tablet)

Levocetirizine dihydrochloride 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 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

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 ■ ½ tablet (2.5 mg) once daily in the evening may be appropriate for less severe symptoms
children 6-11 years of age	■ take ½ tablet (2.5 mg) once daily in the evening ■ do not take more than ½ tablet (2.5 mg) in 24 hours
children under 6 years of age	■ do not use
consumers with kidney disease	■ do not use

(Note: Age ranges are bolded in the draft container labeling for tablet bottle)

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 anhydrous silica, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, titanium dioxide

Questions or comments?

call 1-855-314-1850

PRINCIPAL DISPLAY PANEL

40 x 2500's Tablets

Levocetirizine dihydrochloride Tablets USP 5 mg

NDC 42571-312-53

BATCH NO. : VCAG001

MANF. DATE : 03/2019

EXP. DATE : 02/2022

Tablets to be re-packed within 12 months
from the date of manufacturing.

Store between 20° and 25°C (68° and 77°F)
[see USP Controlled Room Temperature].

Manufactured By:
Micro Labs Limited
Gca-403 722, INDIA.

Manufactured for:
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M. L.: 651

USO-197



ALLERGY RELIEF 24HR

levocetirizine dihydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73226-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVO CETIRIZINE DIHYDROCHLORIDE (UNII: SOD6A38AGA) (LEVOCETIRIZINE - UNII:6U5EA9RT2O)	LEVOCETIRIZINE DIHYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	2 pieces
Shape	OVAL	Size	8mm
Flavor		Imprint Code	X;X
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73226-001-00	40 in 1 CARTON	07/02/2019	
1		2500 in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211551	07/02/2019	

Labeler - Vitesse Pharma LLC (102376674)

Revised: 1/2021

Vitesse Pharma LLC