ALLERGY RELIEF- levocetirizine dihydrochloride tablet, film coated Meijer Distribution Inc

Meijer Distribution, Inc. Allergy Relief 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
- itchy, watery eyes
- sneezing
- itching of the nose or throat

Warnings

Do not use

- if you have <u>kidney disease</u>
- 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

11.0-	
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

Other information

- store between 20° and 25°C (68° and 77°F)
- do not use if printed foil under cap is broken or missing

Inactive ingredients

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

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to XYZAL® Allergy 24HR active ingredient ORIGINAL PRESCRIPTION STRENGTH allergy relief Levocetirizine

Dihydrochloride Tablets, 5 mg

Antihistamine

24 HOUR RELIEF OF:

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

35 Tablets

actual size



ALLERGY RELIEF

levocetirizine dihydrochloride tablet, film coated

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:41250-488

ORAL

Active Ingredient/Active Moiety						
Ingredient Name	Basis of Strength	Strength				
LEVO CETIRIZINE DIHYDRO CHLO RIDE (UNII: SOD6 A38 AGA) (LEVO CETIRIZINE - UNII: 6 U5EA9 RT2O)	LEVOCETIRIZINE DIHYDROCHLORIDE	5 mg				

Inactive Ingredients						
Ingredient Name	Strength					
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)						
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)						
MAGNESIUM STEARATE (UNII: 70097M6I30)						
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)						
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)						
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)						

Product Characteristics						
Color	WHITE	Score	2 pieces			
Shape	OVAL	Size	8mm			
Flavor		Imprint Code	L9CZ;5			
Contains						

P	Packaging								
#	Item Code	Package Description	Marketing Start Date	Marketing End Date					
1	NDC:41250-488-01	1 in 1 CARTON	02/08/2020						
1		35 in 1 BOTTLE; Type 0: Not a Combination Product							
2	NDC:41250-488-27	1 in 1 CARTON	02/06/2020						
2		80 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	ANDA211983	02/06/2020					

Labeler - Meijer Distribution Inc (006959555)

Revised: 3/2020 Meijer Distribution Inc