TOPCARE ALL DAY ALLERGY- levocetirizine dihydrochloride tablet, film coated Topco Associates LLC

Topco Associates LLC. All Day Allergy 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

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 blister unit is broken or torn

Inactive ingredients

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

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

COMPARE TO XYZAL® ALLERGY 24HR ACTIVE INGREDIENT ORIGINAL PRESCRIPTION STRENGTH All Day Allergy LEVOCETIRIZINE DIHYDROCHLORIDE TABLETS, 5 mg

ANTIHISTAMINE

OUR PHARMACISTS RECOMMEND

INDOOR & OUTDOOR ALLERGIES

24 HOUR

RELIEF OF:

Sneezing

Runny Nose

Itchy Nose or throat

Itchy, Watery Eyes

10 TABLETS

actual size



TOPCARE ALL DAY ALLERGY

levocetirizine dihydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-241
Route of Administration	ORAL		

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

Inactive Ingredients		
Ingredient Name	Strength	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
LACTO SE MO NO HYDRATE (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				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-241-01	1 in 1 CARTON	02/05/2020	
1		35 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:36800-241-46	10 in 1 CARTON	03/09/2020	
2		1 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	ANDA211983	02/05/2020	

Labeler - Topco Associates LLC (006935977)

Revised: 3/2020 Topco Associates LLC