# TOPCARE ALL DAY ALLERGY- levocetirizine dihydrochloride tablet, film coated

Topco Associates LLC

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## 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	<ul> <li>take 1 tablet (5 mg) once daily in the evening</li> <li>do not take more than 1 tablet (5 mg) in 24 hours</li> <li>½ tablet (2.5 mg) once daily in the evening may be appropriate for less severe symptoms</li> </ul>
children 6-11 years of age	<ul> <li>take ½ tablet (2.5 mg) once daily in the evening</li> <li>do not take more than ½ tablet (2.5 mg) in 24 hours</li> </ul>
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

TopCare<sub>®</sub> health

COMPARE TO XYZAL® ALLERGY 24HR ACTIVE INGREDIENT

ORIGINAL PRESCRIPTION STRENGTH

All Day Allergy

LEVOCETIRIZINE DIHYDROCHLORIDE TABLETS, 5 mg

**ANTIHISTAMINE** 

**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	
LEVOCETIRIZINE DIHYDROCHLORIDE (UNII: SOD6A38AGA) (LEVOCETIRIZINE - UNII:6U5EA9RT2O)	LEVOCETIRIZ INE DIHYDROCHLORIDE	5 mg	

Inactive Ingredients		
Ingredient Name	Strength	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

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: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		
3	NDC:36800-241- 95	1 in 1 CARTON	10/07/2020	
3		45 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	02/05/2020	

## Labeler - Topco Associates LLC (006935977)

Revised: 2/2022 Topco Associates LLC