

LEVOCETIRIZINE DIHYDROCHLORIDE - levocetirizine dihydrochloride tablet, film coated
Camber Consumer Care Inc

Levocetirizine Dihydrochloride Tablets USP, 5 mg (OTC)

ACTIVE INGREDIENT(S)

Levocetirizine dihydrochloride USP 5 mg

PURPOSE

Antihistamine

USE(S)

temporarily relieves these symptoms due to hay fever or other respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

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	<ul style="list-style-type: none">ask a doctor
adults and children 12 to 64 years of age	<ul style="list-style-type: none">take 1 tablet (5 mg) once daily in the eveningdo not take more than 1 tablet (5 mg) in 24 hours½ tablet (2.5 mg) once daily in the evening may be appropriate for less severe symptoms
children 6 to 11 years of age	<ul style="list-style-type: none">take ½ tablet (2.5 mg) once daily in the eveningdo not take more than ½ tablet (2.5 mg) in 24 hours
children under 6 years of age	<ul style="list-style-type: none">do not use
consumers with kidney disease	<ul style="list-style-type: none">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
- safety sealed: do not use if carton was opened or if individual blister unit is open or torn

INACTIVE INGREDIENTS

colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide.

QUESTIONS or COMMENTS?

call **1-888-588-1418**.

Distributed by:
Camber Consumer Care, Inc.
Piscataway, NJ 08854, USA.

PRINCIPAL DISPLAY PANEL

Levocetirizine Dihydrochloride Tablets USP 5 mg-35's Container carton

Compare to XYZAL[®] Allergy 24HR Active Ingredient*

Allergy Relief

Levocetirizine Dihydrochloride
Tablets, USP

5 mg

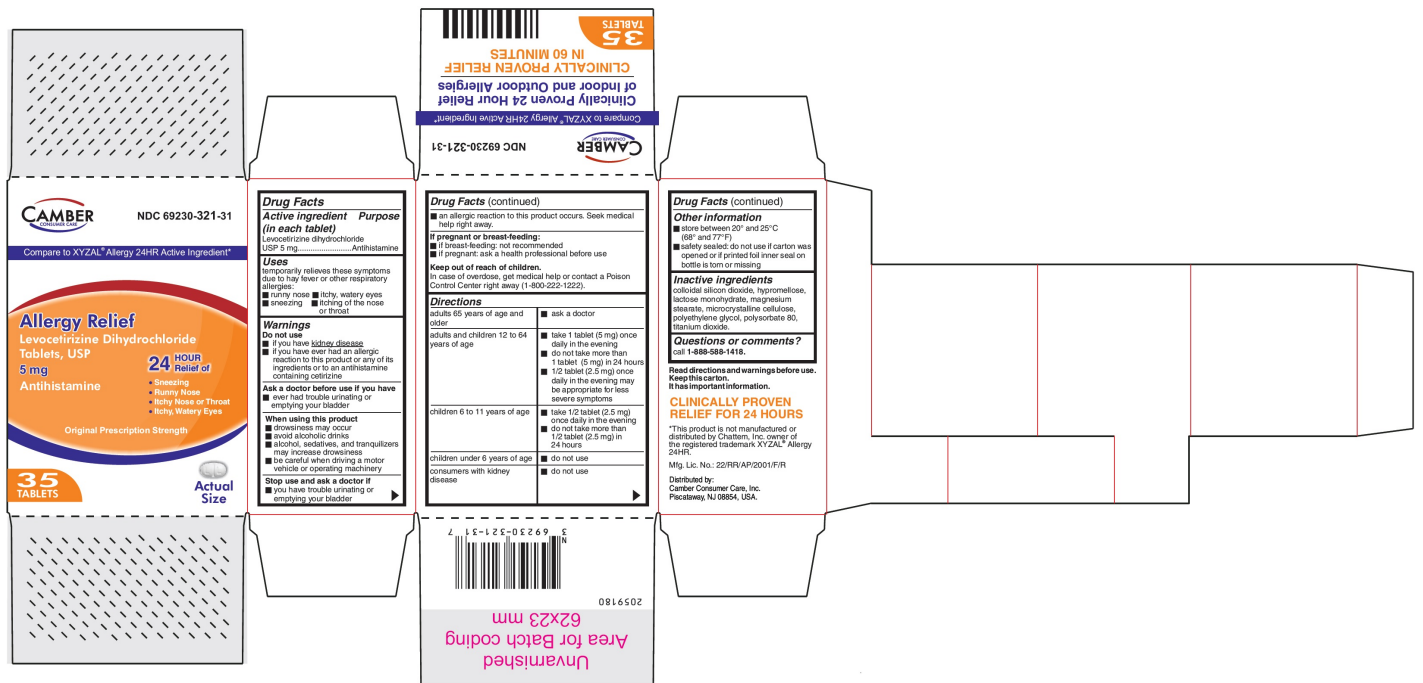
Antihistamine

24 HOUR Relief of

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

Original Prescription Strength

35 TABLETS



Levocetirizine Dihydrochloride Tablets USP 5 mg - 35's Container label

Compare to XYZAL[®] Allergy 24HR Active Ingredient*

Allergy Relief

Levocetirizine Dihydrochloride
Tablets, USP

5 mg

Antihistamine

24 HOUR Relief of

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

Original Prescription Strength

35 TABLETS



NDC 69230-321-31

Compare to XYZAL® Allergy 24HR Active Ingredient*

Allergy Relief

Levocetirizine Dihydrochloride Tablets, USP
5 mg
Antihistamine
Original Prescription Strength

35 TABLETS

Actual Size 

24 HOUR Relief of

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



LOT:
EXP:

Un Varnish Area
24x12 mm

2059256

Mfg. Lic. No.: 22/RR/AP/2001/F/R

Distributed by:
Camber Consumer Care, Inc.
Piscataway, NJ 08854, USA.



Active ingredient (in each tablet)

Levocetirizine dihydrochloride USP 5 mg.....Antihistamine

Purpose

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 to 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 to 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, polysorbate 80, titanium dioxide.

Questions or comments?

call 1-888-588-1418.

LEVOCETIRIZINE DIHYDROCHLORIDE

levocetirizine dihydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69230-321
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
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSE 2910 (3 MPAS) (UNII: 0VUT3PMY82)	
HYPROMELLOSE 2910 (6 MPAS) (UNII: 0WZ8WG20P6)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Product Characteristics

Color	WHITE (White to off white)	Score	2 pieces
Shape	OVAL	Size	8mm
Flavor		Imprint Code	H,LL
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69230-321-31	1 in 1 CARTON	10/28/2020	
1		35 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69230-321-32	1 in 1 CARTON	10/28/2020	
2		55 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69230-321-33	1 in 1 CARTON	10/28/2020	
3		80 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69230-321-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/28/2020	
5	NDC:69230-321-01	10 in 1 CARTON	10/28/2020	
5		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:69230-321-34	1 in 1 CARTON	10/28/2020	
6		180 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	ANDA213513	10/28/2020	

Labeler - Camber Consumer Care Inc (079539968)

Establishment

Name	Address	ID/FEI	Business Operations
Hetero Labs Limited Unit III		676162024	ANALYSIS(69230-321) , MANUFACTURE(69230-321)

Revised: 11/2020

Camber Consumer Care Inc