LEVOCETIRIZINE DIHYDROCHLORIDE- levocetirizine dihydrochloride tablet, film coated
Safrel Pharmaceuticals LLC

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	▪ 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 ▪ ½ tablet (2.5 mg) once daily in the evening may be appropriate for less severe symptoms
children 6 to 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)
• 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 **1-844-384-3723.**

Distributed by:
Safrel Pharmaceuticals, LLC

Bridgewater, NJ 08807

www.safrel.com

PRINCIPAL DISPLAY PANEL

Levocetirizine Dihydrochloride Tablets USP 5 mg-180 Tablets

Compare to XYZAL ® Allergy 24HR Active Ingredient*

Allergy Relief

Levocetirizine Dihydrochloride

Tablets, USP

5 mg

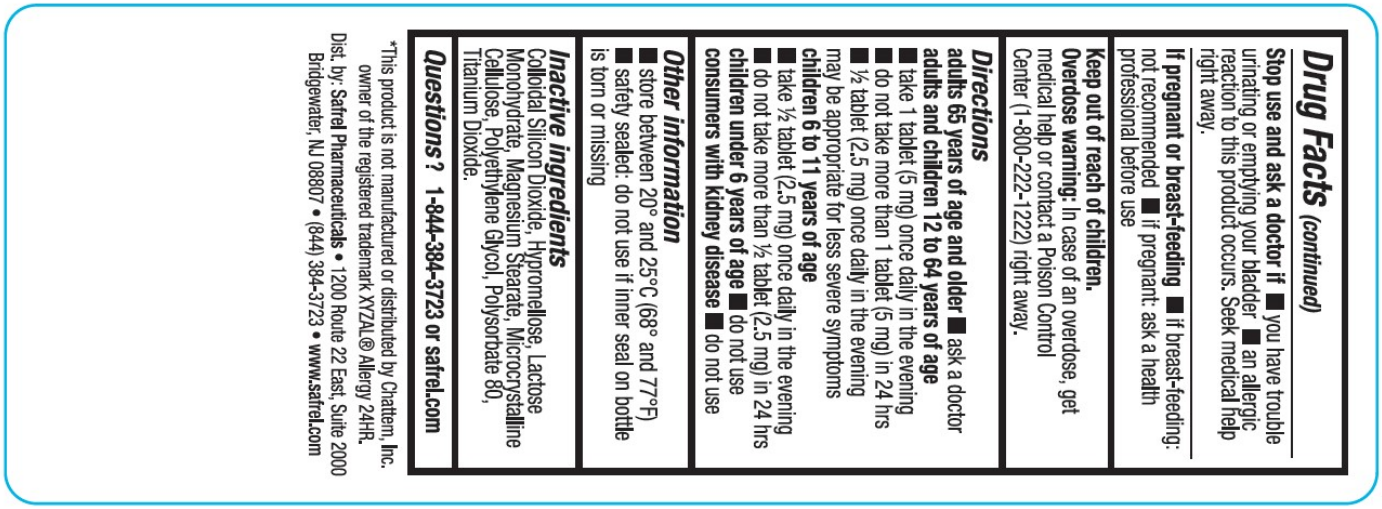
Antihistamine

24 HOUR Relief of
- Sneezing
- Runny Nose

- Itchy Nose or Throat
- Itchy, Watery Eyes

Original Prescription Strength

180 TABLETS



LEVOCETIRIZINE DIHYDROCHLORIDE

levocetirizine dihydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71309-112
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVOCETIRIZINE 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)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
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:71309-112-18	180 in 1 BOTTLE; Type 0: Not a Combination Product	10/28/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA213513	10/28/2022	

Labeler - Safrel Pharmaceuticals LLC (080566287)

Revised: 2/2023 Safrel Pharmaceuticals LLC