

**LEVOCETIRIZINE DIHYDROCHLORIDE- levocetirizine dihydrochloride tablet, film coated**

**Farmacias De Similares TX LLC**

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**Dr. Simi Levocetirizine Dihydrochloride**

***Drug Facts***

***Active ingredient (in each tablet)***

Levocetirizine dihydrochloride USP 5 mg

***Purpose***

Antihistamine

***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***

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**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***

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adults 65  
years of  
age and  
older

■ ask a doctor

■ take 1 tablet (5 mg)  
once daily in the  
evening

adults and  
children 12  
to 64  
years of  
age

■ 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

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***Other information***

- store between 20° and 25°C (68° and 77°F)
- safety sealed: do not use if carton was opened or if individual blister unit is open or

torn

***Inactive ingredients***

Colloidal silicone dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide.

***Questions or comments?***

(855)-280-1079

**Principal Display Panel**

**NDC: 85786-206-30**

DR. SIMI

Allergy Relief

Levocetirizine Dihydrochloride  
Tablets, USP 5 mg

Antihistamine

24 HOUR Relief of: • Sneezing • Runny Nose • Itchy Nose or Throat • Itchy, Watery Eyes

30 Tablets

Compare to XYZAL® 24 HR Active Ingredient\*

\*This product is not manufactured or distributed by Chattem, Inc. owner of the registered trademark XYZAL® Allergy 24HR.

Read directions and warnings before use.

Keep this carton.

It has important information.

Distributed by:  
FARMACIAS DE SIMILARES TX LLC  
800 Brazos St Ste 260, Austin, TX, 78701, USA  
customerservice@drsimi.com  
www.drsimi.com

**Carton labeling**



NDC 85786-206-30



**DR. SIMI**

Compare to XYZAL® Allergy  
24 HR Active Ingredient\*

**Allergy Relief**  
Levocetirizine Dihydrochloride  
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**30 Tablets**

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Active Ingredient (in each tablet)	Purpose
Levocetirizine dihydrochloride USP 5 mg	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 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. ▶

**Drug Facts (continued)**

**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 individual blister unit is open or torn**

**Inactive ingredients**  
Colloidal silicone dioxide, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide.

**Questions or comments?** (855)-280-1079



**DR. SIMI**

Read directions and warnings before use. Keep this carton. It has important information.

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**FARMACIAS DE SIMILARES TX LLC**  
800 Brazos St Ste 260, Austin, TX, 78701, USA  
customerservice@drsimi.com  
www.drsimi.com

Lot:  
Exp:



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levocetirizine dihydrochloride tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85786-206
<b>Route of Administration</b>	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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	H;LL
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85786-206-30	2 in 1 CARTON	04/06/2026	
1		15 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	ANDA213513	04/06/2026	

**Labeler** - Farmacias De Similares TX LLC (119489934)

## Establishment

Name	Address	ID/FEI	Business Operations
Annora Pharma Private Limited		650980746	manufacture(85786-206) , analysis(85786-206)

Revised: 4/2026

Farmacias De Similares TX LLC