

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

**United Natural Foods, Inc. dba UNFI**

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**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**

**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 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"> <li>• ask a doctor</li> </ul>
adults and children 12-64 years of age	<ul style="list-style-type: none"> <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>• 1/2 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 style="list-style-type: none"> <li>• take 1/2 tablet (2.5 mg) once daily in the evening</li> <li>• do not take more than 1/2 tablet (2.5 mg) in 24 hours</li> </ul>
children under 6 years of age	<ul style="list-style-type: none"> <li>• do not use</li> </ul>
consumers with kidney disease	<ul style="list-style-type: none"> <li>• do not use</li> </ul>

### 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, titanium dioxide

### Questions or comments?

Call **1-888-375-3784**

### Carton Label

NDC 41163-938-35

**EQUALINE®**

original prescription strength

**24 hour allergy**

levocetirizine dihydrochloride  
tablets USP, 5 mg  
(antihistamine)

**35 tablets**

**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

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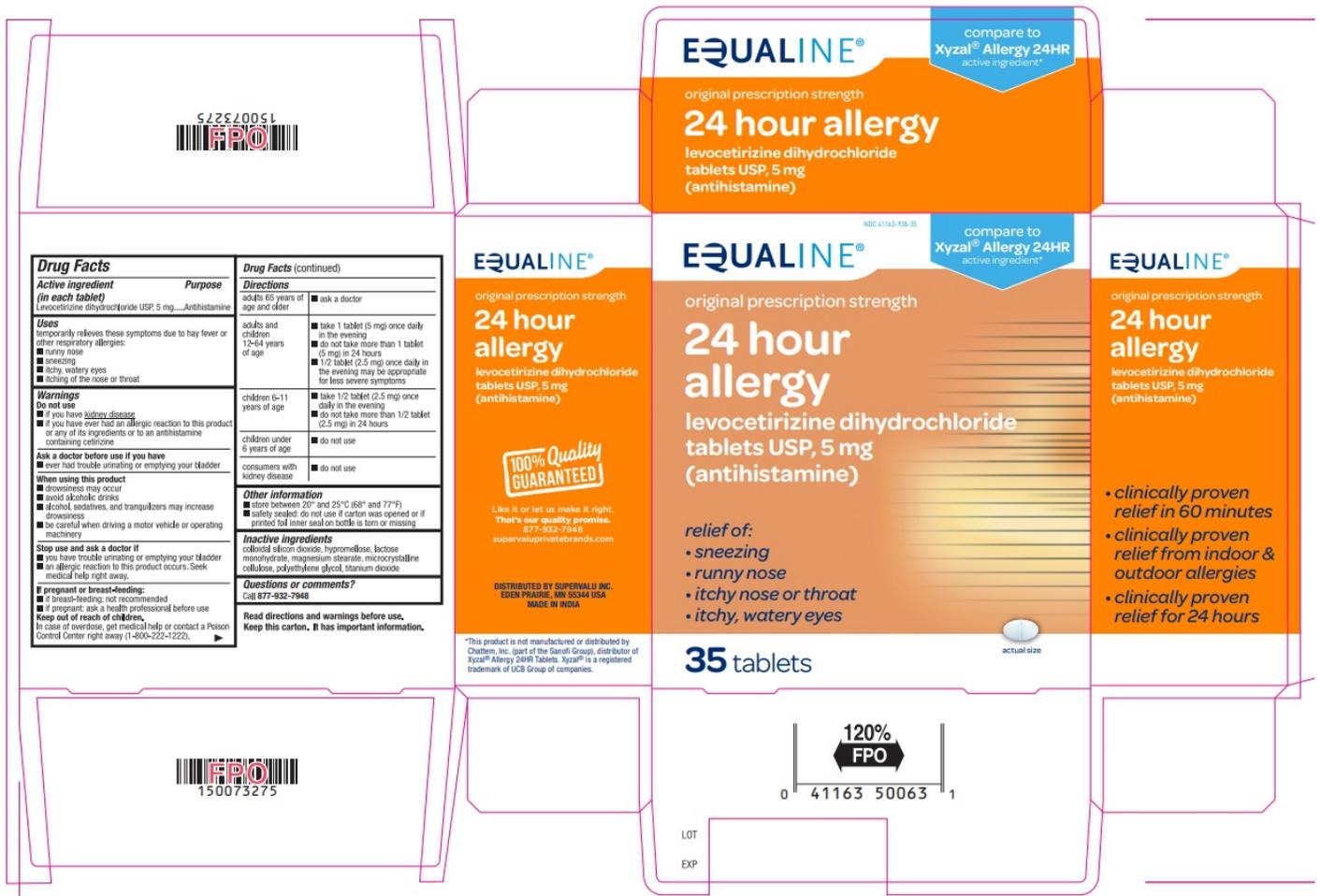
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LOT / EXP

Peel Here



**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 ■ 1/2 tablet (2.5 mg) once daily in the evening may be appropriate for less severe symptoms **children 6-11 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, titanium dioxide **Questions or comments?** call 877-932-7948



# LEVOCETIRIZINE DIHYDROCHLORIDE

levocetirizine dihydrochloride tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41163-938(NDC:43598-735)
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>levocetirizine dihydrochloride</b> (UNII: SOD6A38AGA) (levocetirizine - UNII:6U5EA9RT2O)	levocetirizine dihydrochloride	5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**Polyethylene Glycol, Unspecified** (UNII: 3WJQ0SDW1A)

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	L
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-938-35	1 in 1 CARTON	12/31/2018	
1		35 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	ANDA210375	12/31/2018	

**Labeler** - United Natural Foods, Inc. dba UNFI (943556183)

Revised: 11/2023

United Natural Foods, Inc. dba UNFI