

**CHILDRENS XYZAL ALLERGY- levocetirizine dihydrochloride solution  
Chattem, Inc.**

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**Childrens Xyzal Allergy**

**Children's Xyzal® Allergy 24HR**

**Drug Facts**

**Active ingredient (in each 5 mL)**

**Purpose**

Levocetirizine dihydrochloride 2.5  
mg.....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 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**

- use only with enclosed dosing cup

adults 65 years of age and older	■ ask a doctor
adults and children 12-64 years of age	■ take 5 mL or 10 mL once daily in the evening depending upon severity of symptoms ■ do not take more than 10 mL in 24 hours
children 6-11 years of age	■ take 5 mL once daily in the evening ■ do not take more than 5 mL in 24 hours
children 2-5 years of age	■ take 2.5 mL once daily in the evening ■ do not take more than 2.5 mL in 24 hours
children under 2 years of age	■ do not use
consumers with kidney disease	■ do not use

Note: mL=milliliters

**Other information**

- each 5 mL contains: **sodium 3 mg**
- 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**

flavor, glacial acetic acid, glycerin, maltitol solution, methylparaben, propylparaben, purified water, saccharin sodium, sodium acetate trihydrate

**Questions or comments?**

call **1-866-844-2798**

**PRINCIPAL DISPLAY PANEL**

Children's Xyzal  
Allergy 24HR

Liquid  
Grape Flavor



**PRINCIPAL DISPLAY PANEL**

Children's Xyzal  
Allergy 24HR  
Liquid  
Tutti Frutti Flavor



## CHILDRENS XYZAL ALLERGY

levocetirizine dihydrochloride solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41167-3535
<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	2.5 mg in 5 mL	
Inactive Ingredients				
Ingredient Name		Strength		
ACETIC ACID (UNII: Q40Q9N063P)				
GLYCERIN (UNII: PDC6A3C0OX)				
MALTITOL (UNII: D65DG142WK)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SODIUM ACETATE (UNII: 4550K05C9B)				
Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor	GRAPE	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-3535-0	1 in 1 CARTON	02/01/2023	
1		148 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:41167-3535-1	1 in 1 CARTON	04/01/2023	
2		296 mL in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA209090	02/01/2023		

## CHILDRENS XYZAL ALLERGY

levocetirizine dihydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-3530
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
LEVOCETIRIZINE DIHYDROCHLORIDE (UNII: SOD6A38AGA) (LEVOCETIRIZINE - UNII:6U5EA9RT2O)	LEVOCETIRIZINE DIHYDROCHLORIDE	2.5 mg in 5 mL

**Inactive Ingredients**

Ingredient Name	Strength
ACETIC ACID (UNII: Q40Q9N063P)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTITOL (UNII: D65DG142WK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM ACETATE (UNII: 4550K0SC9B)	

**Product Characteristics**

Color	white	Score	
Shape		Size	
Flavor	TUTTI FRUTTI	Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-3530-1	1 in 1 CARTON	02/01/2023	
1		148 mL in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA209090	02/01/2023	

**Labeler** - Chattem, Inc. (003336013)