

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

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



PRINCIPAL DISPLAY PANEL

Children's Xyzal
 Allergy 24HR
 Liquid
 Bubblegum Flavor



CHILDRENS XYZAL ALLERGY

levocetirizine dihydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-3535
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: 059QF0KOOR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM ACETATE (UNII: 4550K0SC9B)	

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	

CHILDRENS XYZAL ALLERGY

levocetirizine dihydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-3533
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	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-3533-0	1 in 1 CARTON	01/04/2024	
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	01/04/2024	

Labeler - Chattem, Inc. (003336013)