**XYZAL ALLERGY 24HR- levocetirizine dihydrochloride tablet**
**Chattem, Inc.**

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**Xyzal Allergy 24HR**

**Xyzal Allergy 24HR Tablet**

***Drug Facts***

***Active ingredient***

***(in each tablet)***

Levocetirizine dihydrochloride 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 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 12-64 years of age | ■ take 1 tablet (5 mg) once daily in the evening<br>■ do not take more than 1 tablet (5 mg) in 24 hours<br>■ ½ tablet (2.5 mg) once daily in the evening may be appropriate for less severe symptoms |
| children 6-11 years of age | ■ take ½ tablet (2.5 mg) once daily in the evening<br>■ 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 |

*(Note: Age ranges are bolded in the draft container labeling for tablet bottle)*

***Other information***

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

*(if bottled)* safety sealed: do not use if carton was opened or if printed foil inner seal on bottle is torn or missing

*(if stretch card)* safety sealed: do not use if sealed package was torn or opened, or if printed foil inner seal on bottle is torn or missing

***Inactive ingredients***

Colloidal anhydrous silica, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, titanium dioxide

***Questions or comments?***

call **1-800-633-1610**

**PRINCIPAL DISPLAY PANEL**

NDC 41167-3510-0
XYZAL
Allergy 24HR
5 mg
10 Tablets


**PRINCIPAL DISPLAY PANEL**

NDC 41167-3510-1
XYZAL
Allergy 24HR
5 mg
35 Tablets


# XYZAL ALLERGY 24HR

levocetirizine dihydrochloride tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:41167-3510 |
| **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** |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |

| | |
|---|---|
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | white | **Score** | 2 pieces |
| **Shape** | OVAL | **Size** | 8mm |
| **Flavor** | | **Imprint Code** | X;X |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:41167-3510-0 | 1 in 1 CARTON | 03/10/2017 | |
| **1** | | 10 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **2** | NDC:41167-3510-1 | 1 in 1 CARTON | 03/10/2017 | |
| **2** | | 35 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **3** | NDC:41167-3510-2 | 1 in 1 CARTON | 03/10/2017 | |
| **3** | | 55 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **4** | NDC:41167-3510-3 | 1 in 1 CARTON | 03/10/2017 | |
| **4** | | 80 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **5** | NDC:41167-3510-4 | 2 in 1 CARTON | 03/10/2017 | |
| **5** | | 55 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **6** | NDC:41167-3510-5 | 1 in 1 CARTON | 01/04/2024 | |
| **6** | | 45 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 | NDA209089 | 03/10/2017 | |

## Labeler - Chattem, Inc. (003336013)

Revised: 2/2024 Chattem, Inc.