

**CHILDRENS LORATADINE ODT - loratadine tablet, orally disintegrating
WALGREEN CO.**

Loratadine Orally Disintegrating Tablets USP 10 mg

Drug Facts

Active ingredient (in each tablet)

Loratadine USP 10 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

Warnings

Do not use

if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have

liver or kidney disease. Your doctor should determine if you need a different dose.

When using this product

do not take more than directed. Taking more than directed may cause drowsiness.

Stop use and ask a doctor if

an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding,

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 (1-800-222-1222) right away.

Directions

- place 1 tablet on tongue; tablet disintegrates, with or without water

| | |
|--|--|
| adults and children 6 years and over | 1 tablet daily; not more than 1 tablet in 24 hours |
| children under 6 years of age | ask a doctor |
| consumers with liver or kidney disease | ask a doctor |

Other information

- Phenylketonurics: Contains phenylalanine 2.25 mg per tablet
- do not use if the individual blister unit is open or torn
- store at 20° to 25°C (68° to 77°F)
- use tablet immediately after opening individual blister
- Complies with USP test 2 for Disintegration

Inactive ingredients

aspartame, crospovidone, mannitol, microcrystalline cellulose, peppermint, pregelatinized starch (maize), sodium stearyl fumarate

Questions or comments?

call **1-855-274-4122**

DISTRIBUTED BY:
WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015

Walgreens
100% SATISFACTION
GUARANTEED

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MADE IN INDIA

Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg, Blister Carton 30 (3 x 10) Orally Disintegrating Tablets

NDC 0363-4020-84

Walgreens

**Compare to the active ingredient
in Claritin® RediTabs®††**

Junior's

Allergy Relief

**LORATADINE ORALLY DISINTEGRATING
TABLETS USP 10 mg / ANTIHISTAMINE**

Dissolvable Tablet

Non-Drowsy* 24 Hour

- Melts in mouth with no water needed
- 24-hour relief of sneezing, runny nose, itchy, watery eyes & itchy throat or nose
- Indoor & outdoor allergies

AGES 6 YEARS & OLDER

**30 ORALLY DISINTEGRATING
TABLETS**

ACTUAL SIZE

***WHEN TAKEN AS DIRECTED. SEE DRUG FACTS PANEL.**



CHILDRENS LORATADINE ODT

loratadine tablet, orally disintegrating

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0363-4020 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | | | |
|--|----------------------------|---|----------------------|--------------------|
| LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN) | | | LORATADINE | 10 mg |
| | | | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| ASPARTAME (UNII: Z0H242BBR1) | | | | |
| CROSPVIDONE (120 .MU.M) (UNII: 68401960MK) | | | | |
| MANNITOL (UNII: 3OWL53L36A) | | | | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | | | | |
| PEPPERMINT (UNII: V95R5KMY2B) | | | | |
| STARCH, CORN (UNII: O8232NY3SJ) | | | | |
| SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI) | | | | |
| | | | | |
| Product Characteristics | | | | |
| Color | WHITE (White to Off-white) | Score | no score | |
| Shape | ROUND (Biconvex) | Size | 8mm | |
| Flavor | PEPPERMINT | Imprint Code | K;9 | |
| Contains | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:0363-4020-84 | 3 in 1 CARTON | 04/11/2018 | |
| 1 | | 10 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 | | ANDA208477 | 04/11/2018 | |

Labeler - WALGREEN CO. (008965063)

Registrant - Aurohealth LLC (078728447)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|--|
| Aurobindo Pharma Limited | | 650381903 | ANALYSIS(0363-4020) , MANUFACTURE(0363-4020) |