

**LORATADINE ODT - loratadine tablet, orally disintegrating
CVS Pharmacy, Inc.**

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**

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one CVS Drive, Woonsocket, RI 02895

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V-31735

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PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 10 mg, Blister Carton 10 (1 X 10) Orally Disintegrating Tablets

♥CVS Health®

Compare to the active

ingredient in Claritin® RediTabs®†

Indoor & Outdoor Allergies

NDC 69842-085-03

Original Prescription Strength

Non-Drowsy*

Allergy Relief

LORATADINE ORALLY DISINTEGRATING

TABLETS USP 10 mg

Antihistamine

24

HOUR

Relief of:

- Sneezing
- Runny nose
- Itchy, watery eyes
- Itchy throat or nose

Actual Size

No Water

Needed, Melts

in Your Mouth

10 TABLETS

(1 X 10) Orally Disintegrating Tablets

*When taken as directed. See Drug Facts Panel.

1/2"

Drug Facts

Active ingredient (in each tablet) Loratadine USP 10 mg.....Antihistamine

Purpose temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ itchy, watery eyes ■ runny nose ■ sneezing ■ 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.

Drug Facts (continued)

Other information: 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, croscopollose, mannitol, microcrystalline cellulose, peppermint, pregelatinized starch (maize), sodium stearyl fumarate

Questions or comments? call 1-855-274-4122

This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of Claritin® RediTabs™.

CVS Health. Indoor & Outdoor Allergies

Original Prescription Strength Non-Drowsy*  *When taken as directed, See Drug Facts Panel.

Allergy Relief 10 TABLETS (1 x 10) Orally Disintegrating Tablets

CVS Health. Indoor & Outdoor Allergies

Original Prescription Strength Non-Drowsy*  Compare to the active ingredient in Claritin® RediTabs®†

Allergy Relief NDC 69842-085-03

LORATADINE ORALLY DISINTEGRATING TABLETS USP 10 mg Antihistamine

Relief of:

- Sneezing
- Runny nose
- Itchy, watery eyes
- Itchy throat or nose

10 TABLETS (1 x 10) Orally Disintegrating Tablets *When taken as directed, See Drug Facts Panel.

No Water Needed, Melts in Your Mouth

 Actual Size



LM-5158... P105161Z
No Coating Area
Lot: Exp:

Instructions for Opening Blister Pack Code: TS/DRUGS/22/2009

Do not push the tablet from the back 

1. Bend and tear blister at perforation 

2. Peel off the foil. Gently push tablet out. 

3. Place the tablet on tongue and close mouth. The tablet will disintegrate. 

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#344125

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

♥CVS Health®

Compare to the active

ingredient in Claritin® RediTabs®†

Indoor &Outdoor Allergies

NDC 69842-085-09

Original Prescription Strength

Non-Drowsy*

Allergy Relief

LORATADINE ORALLY DISINTEGRATING

TABLETS USP 10 mg

Antihistamine

24

HOUR

Relief of:

- Sneezing
- Runny nose
- Itchy, watery eyes
- Itchy throat or nose

Actual Size

No Water

Needed, Melts

in Your Mouth

30 TABLETS

(3 X 10) ORALLY DISINTEGRATING TABLETS

*When taken as directed. See Drug Facts Panel.

GLUE - NO COATING

This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of Claritin® RediTabs®.

Questions or comments? call 1-855-274-1122

Inactive ingredients: Contains phenylalanine 2.25 mg per tablet
 aspartame, croscollonized starch (maize), sodium stearyl fumarate
 peppermint, pregelatinized starch (maize), sodium stearoyl fumarate

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

Other Information: Contains phenylalanine 2.25 mg per tablet

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

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

Drug Facts (continued)

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.
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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

Active ingredient (in each tablet)
 Loratadine USP 10 mg
 Antihistamine

Purpose
 Antihistamine

Drug Facts
 Active ingredient (in each tablet)
 Loratadine USP 10 mg
 Antihistamine

Drug Facts
 Active ingredient (in each tablet)
 Loratadine USP 10 mg
 Antihistamine

CVS Health. Indoor & Outdoor Allergies

Original Prescription Strength
 Non-Drowsy*
Allergy Relief
 LORATADINE ORALLY DISINTEGRATING TABLETS USP 10 mg
 Antihistamine

24 HOUR

30 TABLETS
 (3 X 10) ORALLY DISINTEGRATING TABLETS

*When taken as directed. See Drug Facts Panel.

CVS Health. Compare to the active ingredient in Claritin® RediTabs®†

Indoor & Outdoor Allergies

NDC 60842-085-09

Original Prescription Strength
 Non-Drowsy*
Allergy Relief
 LORATADINE ORALLY DISINTEGRATING TABLETS USP 10 mg
 Antihistamine

24 HOUR

30 TABLETS
 (3 X 10) ORALLY DISINTEGRATING TABLETS

Relief of:

- Sneezing
- Runny nose
- Itchy, watery eyes
- Itchy throat or nose

No Water Needed, Melts in Your Mouth

Actual Size

Unnumbered Zone (dotted line not for printing) 71 x 25 mm

*When taken as directed. See Drug Facts Panel.

INSTRUCTIONS FOR OPENING BLISTER PACK

1. Bend and tear blister at perforation.
2. Peel off the foil. Gently push tablet out.
3. Place the tablet on tongue and close mouth. The tablet will disintegrate.

Do not push the tablet from the back.

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LORATADINE ODT
 loratadine tablet, orally disintegrating

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-085
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)	
CROSPROVIDONE (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:69842-085-03	1 in 1 CARTON	04/11/2018	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69842-085-09	3 in 1 CARTON	04/11/2018	
2		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 - CVS Pharmacy, Inc. (062312574)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(69842-085) , MANUFACTURE(69842-085)

Revised: 3/2025

CVS Pharmacy, Inc.