

**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**

Distributed by: CVS Pharmacy, Inc.

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

LORTADINE ORALLY DISINTEGRATING

TABLETS USP 10 mg

Antihistamine

No Water Needed Melts in Your Mouth

24 Hour

Relief of:

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

*When taken as directed. See Drug Facts Panel.

10 TABLETS

10 (1 X 10) Orally Disintegrating Tablets

1 1/2"

Drug Facts

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

Purpose Antihistamine

Uses 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)

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
 ■ Phenylethanolamines: Contains phenylethanolamine 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

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*

Allergy Relief 

10 TABLETS (1 x 10) Orally Disintegrating Tablets

*When taken as directed. See Drug Facts Panel.

CVS Health.

Indoor & Outdoor Allergies

Compare to the active ingredient in Claritin® RediTabs®†

DNB 69842-085-03

Original Prescription Strength
Non-Drowsy*

Allergy Relief 

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 




Lot: Exp:


LM=5158 P1051617


No Coating Area


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

**CVS HEALTH™
NDC XXXX-XXXX**

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

Indoor & Outdoor Allergies

Original Prescription Strength

Non-Drowsy*

Allergy Relief

Loratadine Orally Disintegrating

Tablets USP 10 mg

Antihistamine

No Water Needed Melts in Your Mouth

24 Hour

Relief of:

- *Sneezing*
- *Runny Nose*
- *Itchy, Watery Eyes*
- *Itchy Throat or Nose*

**When taken as directed. See Drug Facts Panel.*

10 (1 X 10) Orally Disintegrating Tablets

Drug Facts

Active ingredient (in each tablet) Loratadine HCl (10 mg)

Purpose Antihistamine

Uses Temporarily relieves these symptoms due to hay fever or other upper respiratory tract allergies:

- sneezing
- runny nose
- itchy, watery eyes
- itchy throat or nose

Warnings

- Do not take if you have ever had a severe allergic reaction to this product or any of its ingredients.
- Ask your doctor before you take this medicine if you have ever had a severe allergic reaction to any medicine or drug, or if you are taking any other medicine.
- Your doctor should determine if you should take this medicine.
- When taking this medicine, you may feel drowsy. Do not drive or operate machinery until you know how this medicine affects you.
- Alcohol may cause drowsiness.
- When taking this medicine, you may feel drowsy. Do not drive or operate machinery until you know how this medicine affects you.
- Keep out of the reach of children. Tell them not to take this medicine if they feel sick or if they have a fever.

Other information

- Keep out of the reach of children. Tell them not to take this medicine if they feel sick or if they have a fever.
- Keep out of the reach of children. Tell them not to take this medicine if they feel sick or if they have a fever.
- Keep out of the reach of children. Tell them not to take this medicine if they feel sick or if they have a fever.

Drug Facts (continued)

Directions	See back of box for directions. Do not take more than 10 mg per day.
Warnings	See back of box for warnings. Do not take more than 10 mg per day.
Other information	See back of box for other information. Do not take more than 10 mg per day.

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CVSHealth.

Original Prescription Strength
Non-Drowsy*

Allergy Relief

LORATADINE ORALLY DISINTEGRATING TABLETS 10 mg
Antihistamine

No water needed, melts in your mouth

24 HOUR

Indoor & Outdoor Allergies

*When taken as directed. See Drug Facts Panel.

CVSHealth.

Compare to the active ingredient in Claritin® RedTabs

Indoor & Outdoor Allergies

NDC 100-100-1000

Original Prescription Strength
Non-Drowsy*

Allergy Relief

LORATADINE ORALLY DISINTEGRATING TABLETS 10 mg
Antihistamine

No water needed, melts in your mouth

24 HOUR

Relief of:

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

Actual Size

30 (3 X 10) ORALLY DISINTEGRATING TABLETS

*When taken as directed. See Drug Facts Panel.

Lot: _____
EXP: _____

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Instructions for Opening Blister Pack

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.

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: 7/2023

CVS Pharmacy, Inc.