

This label may not be the latest approved by FDA.
For more labeling information, please visit <https://www.fda.gov/drugs/labeling>

NDA 21-512
Draft Labeling
Push Through Blister Package
4 Count

LORATADINE 10 mg
1 TABLET

**PUSH TABLET
THROUGH FOIL**

MANUFACTURED BY PERRIGO
ALLEGAN, MI 49010 USA

27584 FA X1-10

LOT#

EXP. DATE:

LORATADINE 10 mg
1 TABLET

**PUSH TABLET
THROUGH FOIL**

MANUFACTURED BY PERRIGO
ALLEGAN, MI 49010 USA

27584 FA X1-10

LOT#

EXP. DATE:

LORATADINE 10 mg
1 TABLET

**PUSH TABLET
THROUGH FOIL**

MANUFACTURED BY PERRIGO
ALLEGAN, MI 49010 USA

27584 FA X1-10

LOT#

EXP. DATE:

LORATADINE 10 mg
1 TABLET

**PUSH TABLET
THROUGH FOIL**

MANUFACTURED BY PERRIGO
ALLEGAN, MI 49010 USA

27584 FA X1-10

LOT#

EXP. DATE:

Label may not be the latest approved by FDA. For the latest information, please visit <https://www.fda.gov>

NDA 21-512

Draft Labeling

Push Through Blister Package

12 Count

LORATADINE 10 mg 1 TABLET PUSH TABLET THROUGH FOIL MANUFACTURED BY PERRIGO ALLEGAN, MI 49010 USA LOT# EXP. DATE:	LORATADINE 10 mg 1 TABLET PUSH TABLET THROUGH FOIL MANUFACTURED BY PERRIGO ALLEGAN, MI 49010 USA LOT# EXP. DATE:	LORATADINE 10 mg 1 TABLET PUSH TABLET THROUGH FOIL MANUFACTURED BY PERRIGO ALLEGAN, MI 49010 USA LOT# EXP. DATE:
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LORATADINE 10 mg 1 TABLET PUSH TABLET THROUGH FOIL MANUFACTURED BY PERRIGO ALLEGAN, MI 49010 USA LOT# EXP. DATE:	LORATADINE 10 mg 1 TABLET PUSH TABLET THROUGH FOIL MANUFACTURED BY PERRIGO ALLEGAN, MI 49010 USA LOT# EXP. DATE:	LORATADINE 10 mg 1 TABLET PUSH TABLET THROUGH FOIL MANUFACTURED BY PERRIGO ALLEGAN, MI 49010 USA LOT# EXP. DATE:
LORATADINE 10 mg 1 TABLET PUSH TABLET THROUGH FOIL MANUFACTURED BY PERRIGO ALLEGAN, MI 49010 USA LOT# EXP. DATE:	LORATADINE 10 mg 1 TABLET PUSH TABLET THROUGH FOIL MANUFACTURED BY PERRIGO ALLEGAN, MI 49010 USA LOT# EXP. DATE:	LORATADINE 10 mg 1 TABLET PUSH TABLET THROUGH FOIL MANUFACTURED BY PERRIGO ALLEGAN, MI 49010 USA LOT# EXP. DATE:

NDA 21-512
Draft Labeling
Blister Carton
4 Count

EFB 186

MANUFACTURED BY
PERIGO
ALLEGAN, MI 49010 U.S.A.

If you have questions of a medical nature,
please contact your pharmacist, doctor or
health care professional.

Inactive ingredients lactose monohydrate,
magnesium stearate, povidone, pregelatinized starch

Other information
■ protect from excessive moisture
■ store at 20°-25°C (68°-77°F)
■ do not use if individual blister is open or torn

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

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.
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
right away.

Drug Facts
Active ingredient (in each tablet) Purpose
Loratadine 10 mg.....Antihistamine
Uses
temporarily relieves these symptoms due
to hay fever or other upper respiratory allergies:
■ sneezing
■ itchy, watery eyes
■ itchy, watery nose
■ 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
right away.

Non-Drowsy 24 Hour
Loratadine Tablets, 10 mg
Antihistamine
*When taken as directed.
See Drug Facts Panel.

NEW!
Original Prescription Strength
Non-Drowsy*
Compare to the
active ingredient
in Claritin® Tablets
Loratadine
Tablets, 10 mg
Antihistamine
24 Hour
Relief of:
☒ Sneezing ☒ Itchy, watery eyes
☒ Runny nose ☒ Itchy throat or nose
4 Tablets
*When taken as directed. See Drug Facts Panel.

Code Area
27584 FA C4-1
0 000000 000000 0

FORMAT: STANDARD
TYPE SIZES:
TITLE: 10 pt Helvetica Bold Cond. Italic
TITLE (continued): 8 pt Helvetica Bold Cond. Italic
(continued) 8 pt Helvetica Cond. Medium
HEADINGS: 8 pt Helvetica Bold Cond. Italic
SUBHEADINGS: 6 pt Helvetica Bold
TEXT: 6 pt Helvetica Cond. Medium
LEADING: 6.5 pt
BULLETS: 5 pt Square with
2 M'S spacing between statements
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

NDA 21-512
Draft Labeling
Blister Carton
12 Count

EFB 186

MANUFACTURED BY
PERRIGO
ALLEGAN, MI 49010 U.S.A.

Drug Facts

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

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

Drug Facts (continued)

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

Other information
■ do not use if individual blister is open or torn
■ store at 20°-25°C (68°-77°F)
■ protect from excessive moisture

Inactive ingredients lactose monohydrate, magnesium stearate, povidone, pregelatinized starch

If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.

Non-Drowsy* 24 Hour
Loratadine Tablets, 10 mg
Antihistamine
*When taken as directed. See Drug Facts Panel.

Non-Drowsy* 24 Hour
Loratadine Tablets, 10 mg
Antihistamine
*When taken as directed. See Drug Facts Panel.

NEW!
Original Prescription Strength
Non-Drowsy*

12 days of relief
Compare to the active ingredient in Claritin® Tablets

Loratadine Tablets, 10 mg
Antihistamine

24 Hour

Relief of:
☒ Sneezing ☒ Itchy, watery eyes
☒ Runny nose ☒ Itchy throat or nose

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

Actual Size

CONVENIENT RECLOSING TAB



FORMAT: STANDARD

TYPE SIZES:
TITLE: 10 pt Helvetica Bold Cond. Italic
TITLE (continued): 8 pt Helvetica Bold Cond. Italic (continued) 8 pt Helvetica Cond. Medium
HEADINGS: 8 pt Helvetica Bold Cond. Italic
SUBHEADINGS: 6 pt Helvetica Bold
TEXT: 6 pt Helvetica Cond. Medium
LEADING: 6.5 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Code Area

NDA 21-512

Draft Labeling

Bottle Label

10 Count

ELA 17A

Non-Drowsy

Loratadine Tablets, 10 mg

Antihistamine

**24
Hour**

10 Tablets

*When taken
as directed.

Sealed with printed foil under cap

Active ingredient

Purpose

Loratadine 10 mg..... 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

you have the most serious allergic reaction,

ask your health professional for help. **Keep**

out of reach of children. In case of

overdose, get medical help or contact a

Poison Control Center right away.

Directions

■ **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

■ **patients with liver or**

kidney disease: ask a doctor

Store at 20-25°C (68-77°F).

MANUFACTURED BY
PERRIGO
ALLEGAN, MI 49010 U.S.A.

**CODE
AREA**

27552 FA F3-1

FORMAT: STANDARD

TYPE SIZES:

TITLE: 4.75 pt Helvetica Cond. Bold Italic

HEADINGS: 4.75 pt Helvetica Cond. Bold Italic

SUBHEADINGS: 4.75 pt Helvetica Bold Cond.

TEXT: 4.75 pt Helvetica Cond. Medium

LEADING: 4.75 pt

**BULLETS: 4.5 pt Square with
2 M'S spacing between statements**

HEAVY LINES: 1 pt

HAIRLINES: 0.5 pt

NDA 21-512
Draft Labeling
Bottle Label
30 Count

ELA 17A

Non-Drowsy*	Loratadine Tablets, 10 mg	Antihistamine	24 Hour	30 Tablets	*When taken as directed.	Sealed with crinkled foil under cap	Active Ingredient (in each tablet)	Purpose Loratadine 10 mg..... Antihistamine	Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:	■ sneezing ■ runny nose ■ 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 you are pregnant, planning to get pregnant, or breastfeeding, keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	Directions ■ 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 Store at 20°-25°C (68°-77°F).	MANUFACTURED BY PERRIGO® ALLEGAN, MI 49010 U.S.A.	CODE AREA	 27565 FA F1-3
Active Ingredient (in each tablet)							Purpose Loratadine 10 mg..... Antihistamine	Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:	■ sneezing ■ runny nose ■ 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 you are pregnant, planning to get pregnant, or breastfeeding, keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	Directions ■ 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 Store at 20°-25°C (68°-77°F).				

FORMAT: STANDARD

TYPE SIZES:

TITLE: 4.75 pt Helvetica Cond. Bold Italic

HEADINGS: 4.75 pt Helvetica Cond. Bold Italic

SUBHEADINGS: 4.75 pt Helvetica Bold Cond.

TEXT: 4.75 pt Helvetica Cond. Medium

LEADING: 4.75 pt

**BULLETS: 4.5 pt Square with
2 M'S spacing between statements**

HEAVY LINES: 1 pt

HAIRLINES: 0.5 pt

NDA 21-512

Draft Labeling

Bottle Label

300 Count

ELA 17A

Non-Drowsy[®]

Loratadine
Tablets, 10 mg

Antihistamine

24
Hour

300 Tablets

*When taken
as directed.

Sealed with printed foil under cap

Active Ingredient
(in each tablet)
Loratadine 10 mg..... Antihistamine

Purpose
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
you are pregnant, nursing, or taking
other medicines, **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.

Directions
■ **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
Store at 20-25°C (68-77°F).

CODE
AREA
27587 FA F3-3

MANUFACTURED BY
PERRIGO[®]
ALLEGAN, MI 49010 U.S.A.

FORMAT: STANDARD

TYPE SIZES:

TITLE: 4.75 pt Helvetica Cond. Bold Italic

HEADINGS: 4.75 pt Helvetica Cond. Bold Italic

SUBHEADINGS: 4.75 pt Helvetica Bold Cond.

TEXT: 4.75 pt Helvetica Cond. Medium

LEADING: 4.75 pt

**BULLETS: 4.5 pt Square with
2 M'S spacing between statements**

HEAVY LINES: 1 pt

HAIRLINES: 0.5 pt

NDA 21-512
Draft Labeling
Bottle Carton
10 Count

Drug Facts (continued)	
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 right away.	
Directions	
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

	Drug Facts
Purpose	Active ingredient (in each tablet) Loratadine 10 mg.....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.

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

Non-Drowsy*

Loratadine Tablets, 10 mg

Antihistamine

10 Tablets

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

Actual Size

Non-Drowsy*

**10 days
of relief**

Loratadine Tablets, 10 mg

Antihistamine

Relief of:

☒ Sneezing

- ✓ Runny nose

- ✓ Itchy, watery eyes

- ✓ Itchy throat or nose

PERRIGO
MANUFACTURED BY
ALLEGAN, MI 49010 U.S.A.

If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.

Drug Facts (continued)

Other information

- sealed with printed foil under cap for your protection
- store at 20°-25°C (68°-77°F)

Inactive ingredients lactase monohydrate, magnesium stearate, povidone, pregelatinized starch

FORMAT: STANDARD

TYPE SIZES:

TITLE: 10 pt Helvetica Bold Italic

TITLE (continued): 8 pt Helvetica Bold Italic

(continued) **8 pt Helvetica Regular**

HEADINGS: 8 pt Helvetica Bold Italic

SUBHEADINGS: 6 pt Helvetica Bold

TEXT: 6 pt Helvetica Regular

LEADING: 6.5 pt

BULLETS: 5 pt Square with 2 M'S spacing between statements

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

✓ 27552 FA C5-

EXP.

LOT NO

**GODDE
AREIA**

NDA 21-512
Draft Labeling
Bottle Carton
30 Count

Drug Facts (continued)	
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 right away.	
adults and children 6 years and over	1 tablet daily; 1 tablet in 24 hours
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Drug Facts	
Active ingredient (in each tablet)	Antihistamine
Purpose	Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ 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.

Non-Drowsy*

Loratadine Tablets, 10 mg

Antihistamine

30 Tablets

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

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

Non-Drowsy*

**30 days
of relief**

Loratadine Tablets, 10 mg

Antihistamine

Relief of:

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

Actual Size

MANUFACTURED BY
PERIGO
ALLEGAN, MI 49010 U.S.A.

If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.

Drug Facts (continued)

Other information

store at 20°-25°C (68°-77°F)

Sealed with printed toll under cap for your protection.

Inactive ingredients lactose monohydrate, magnesium stearate, povidone, pregelatinized starch

FORMAT: STANDARD

TYPE SIZES:

TITLE: 10 pt Helvetica Bold Italic

TITLE (continued): **8 pt Helvetica Bold Italic**

(continued) **8 pt Helvetica Regular**
HEADINGS: 8 pt Helvetica Bold Italic

SUBHEADINGS: 6 pt Helvetica Bold
TEXT: 6 pt Helvetica Regular

LEADING: 6.5 pt

BULLETS: 5 pt Square with 2 M'S spacing between statements

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

27565 FA C4-

EXP.

LOT NO

C00000000000000000000

NDA 21-512
Draft Labeling
Bottle Carton
300 Count

Drug Facts (continued)	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 right away.
Directions	adults and children 6 years and over 1 tablet daily; 1 tablet in 24 hours children under 6 years of age ask a doctor consumers with liver or kidney disease ask a doctor

Drug Facts	
Active Ingredient (in each tablet)	Loratadine 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.

Non-Drowsy*

Loratadine Tablets, 10 mg

Antihistamine

300 Tablets

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

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

Non-Drowsy*

300 days of relief

Loratadine Tablets, 10 mg

Antihistamine

Relief of:

☒ Sneezing

☒ Runny nose

- ☒ Itchy, watery eyes

☒ Itchy throat or nose

Drug Facts (continued)

Other information

- sealed with printed foil under cap for your protection
- store at 20°-25°C (68°-77°F)
- avoid exposure to moisture

Inactive ingredients lactose monohydrate, magnesium stearate, povidone, pregelatinized starch

If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.

MANUFACTURED BY
3M PERRIGO
 ALLEGANY, MI 49010 U.S.A.

HAIRLINES: 0.5 pt

HAIRLINES: 0.5 pt