

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:

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:

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:
27553 FA X1-1

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:

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
PEREGO
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

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

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

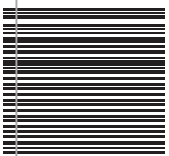
consumers with liver or kidney disease
ask a doctor

Drug Facts

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.



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

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

Code Area
OPEN OTHER END

NEW! Original Prescription Strength
Non-Drowsy* Compare to the active ingredient in Claritin® Tablets
4 days of relief

Loratadine Tablets, 10 mg

Antihistamine

24 Hour

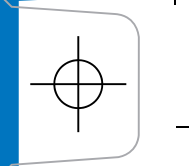
Relief of:

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

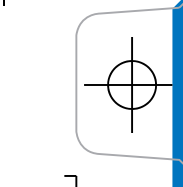
4 Tablets

*When taken as directed. See Drug Facts Panel.

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

EFB 186

MANUFACTURED BY
PERRIGO
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

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

Other information

adults and children 6 years and over
1 tablet daily, not more than 1 tablet in 24 hours

ask a doctor	ask a doctor
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Directions

Drug Facts (continued)

Drug Facts
Loratadine 10 mg.....Antihistamine

Active ingredient (in each tablet) 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.

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.

Loratadine Tablets, 10 mg
24 Hour
Non-Drowsy*
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! 12 days of relief
Original Prescription Strength
Non-Drowsy* Compare to the active ingredient in Claritin® Tablets

Loratadine Tablets, 10 mg

Antihistamine



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

12 Tablets

*When taken as directed. See Drug Facts Panel.

Actual Size



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

27553 FA 02-1

Code Area
OPEN OTHER END

CONVENIENT RECLOSING TAB

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
(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.

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**

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 printed 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.

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 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
health professional before use.
■ **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 F-13

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

Purpose

Loratadine 10 mg..... Antihistamine

Uses

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

- 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 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 health professional before use.

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**

27587 FA F3-3

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**

EFB 350

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. 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
ask a doctor

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; Antihistamine

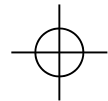
Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: runny nose sneezing itchy, watery eyes itching of the nose or throat

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.



NEW! Original Prescription Strength

Compare to the active ingredient in Claritin® Tablets

Non-Drowsy*

Loratadine Tablets, 10 mg

Antihistamine

24 Hour

10 Tablets

*When taken as directed. See Drug Facts Panel.

Actual Size

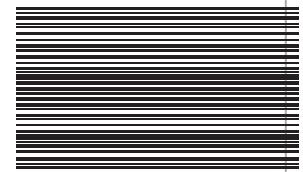
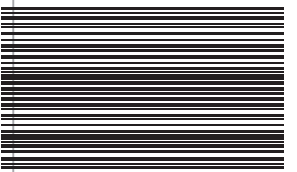
Non-Drowsy* 10 days of relief

Loratadine Tablets, 10 mg

Antihistamine

Relief of:

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



LOT NO. 000000000000000000

EXP. 27552 FA 05-1

CODE AREA

Drug Facts (continued)

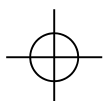
Other information

- sealed with printed foil under cap for your protection
- store at 20°-25°C (68°-77°F)
- lactose monohydrate, magnesium stearate, povidone, pregelatinized starch

Inactive ingredients

MANUFACTURED BY **PERRIGO** ALLEGAN, MI 49010 USA.

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



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

**NDA 21-512
Draft Labeling
Bottle Carton
30 Count**

EFB 350

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
ask a doctor
children under 6 years of age
ask a doctor
ask a doctor

Drug Facts
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.

LOT NO. 00000000000000000000
EXP. AREA
CODE AREA
27565 FA C4-1

NEW! Original Prescription Strength
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
24 Hour
Actual Size 

Non-Drowsy* 30 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)
Inactive ingredients lactose monohydrate, magnesium stearate, povidone, pregeatinized starch
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.

FORMAT: STANDARD
TYPE SIZES:
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(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

NDA 21-512
Draft Labeling
Bottle Carton
300 Count

EFB 350

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
ask a doctor
ask a doctor
ask a doctor

Drug Facts
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.

NEW! Original Prescription Strength

Compare to the active ingredient in Claritin® Tablets

Non-Drowsy*

Loratadine Tablets, 10 mg

Antihistamine

300 Tablets

*When taken as directed. See Drug Facts Panel.

Actual Size 

24 Hour

Non-Drowsy* 300 days of relief

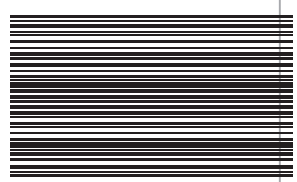
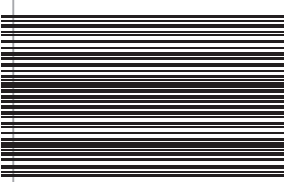
Loratadine Tablets, 10 mg

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)
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 **PERIGO**
ALLEGAN, MI 49010 U.S.A.



LOT NO. 0 000000 000000 0

EXP. AREA

27587 FA 05-1

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