

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-512

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:
---	---	---	---

**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
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

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

Drug Facts (continued)

Drug Facts
 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.

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.

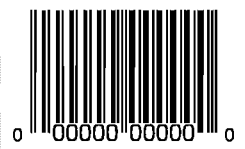
NEW!
 Original Prescription Strength
Non-Drowsy*
 Compare to the
 active ingredient
 in Claritin® Tablets

Loratadine
Tablets, 10 mg
 Antihistamine

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

4 Tablets

*When taken as directed. See Drug Facts Panel.



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

OPEN OTHER END
 Cuts Area

CONVENIENT RECLOSING TAB

27584 FA-C1-1

NDA 21-512
Draft Labeling
Blister Carton
12 Count

EFB 186

MANUFACTURED BY
PERRIGO
ALLEGAN, MI 49010 USA

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

Drug Facts (continued)

Drug Facts
 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.

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.



27559 FA 02-1

Code Area

OPEN OTHER END

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

**NDA 21-512
Draft Labeling
Bottle Label
10 Count**

ELA 17A

<p>Non-Drowsy[*] Loratadine Tablets, 10 mg Antihistamine 24 Hour 10 Tablets</p>	<p>Sealed with oriented foil under cap</p> <p>Active Ingredient (in each tablet) Loratadine 10 mg.....Antihistamine</p> <p>Purpose Loratadine 10 mg.....Antihistamine</p> <p>Uses Primarily relieves these symptoms: runny nose, itchy nose or other upper respiratory allergies:</p> <ul style="list-style-type: none"> ■ runny nose ■ sneezing ■ itchy, watery eyes ■ itching of the nose or throat <p>Warnings 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, you should avoid alcohol. 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 breastfeeding, ask a doctor before using this product. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>Directions ■ adults and children 6 years and over: 1 tablet, not more than 1 tablet in 24 hours</p> <p>■ children under 6 years of age: ask a doctor</p> <p>■ consumers with liver or kidney disease: ask a doctor</p> <p>Store at 25°C (77°F).</p>	<p>MANUFACTURED BY PERRIGO[®] ALLEGAN, MI 48801 U.S.A.</p> <p>CODE AREA</p> <p>27552 FA P3-1</p>
---	---	---

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

<p>Non-Drowsy* Loratadine Tablets, 10 mg Antihistamine 24 Hour 30 Tablets <small>*When taken as directed.</small></p>	<p><small>Sealed with printed foil under cap.</small> Active ingredient (in each tablet) Loratadine 10 mg Antihistamine</p> <p>Purpose Loratadine 10 mg Antihistamine</p> <p>Uses Loratadine 10 mg Antihistamine</p> <p>How to use Loratadine 10 mg Antihistamine</p> <p>Warnings Loratadine 10 mg Antihistamine</p> <p>Directions Loratadine 10 mg Antihistamine</p> <p>Other information Loratadine 10 mg Antihistamine</p>	<p>MANUFACTURED BY PERRIGO ALLEGAN, MI 49010 U.S.A.</p> <p>CODE AREA</p> <p>27565 FA F1-3</p>
---	---	--

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

<p>Non-Drowsy[®] Loratadine Tablets, 10 mg Antihistamine 24 Hour 300 Tablets</p>	<p>Sealed with prilled foil under cap (for each tablet)</p> <p>Active Ingredient Loratadine, 10 mg.....Antihistamine</p> <p>Use temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <ul style="list-style-type: none"> ■ runny nose ■ sneezing ■ itching of the nose or throat </p> <p>Warnings Do not use if you have ever had an allergic reaction to this product or any of its ingredients. Ask a doctor before using this product if you are pregnant or nursing. 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 you experience severe dizziness or faintness. Seek medical help right away, if frequent 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.</p> <p>Directions <ul style="list-style-type: none"> ■ 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 </p> <p>Caution <ul style="list-style-type: none"> ■ May impair judgment with liver or kidney disease; ask a doctor </p> <p>Store at 20-25°C (68-77°F).</p>	<p>MANUFACTURED BY PERRIGO[®] ALLEGAN, MI 48800 U.S.A.</p> <p>CODE AREA</p> <p>27587 FA F3-3</p>
--	--	---

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



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
 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.

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

24 Hour

30 Tablets

*When taken as directed. See Drug Facts Panel.

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
PERRIGO
 ALLEGAN, MI 49010 U.S.A.

Code Area

LOT NO. 000000000000
 EXP. 27565 FA CA-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

NDA 21-512
Draft Labeling
Bottle Carton
300 Count

EFB 350

<p>Drug Facts (continued)</p> <p>When using this product do not take more than directed. Taking more than directed may cause drowsiness.</p> <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p> <p>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.</p> <p>Directions</p> <p>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 consumers with liver or kidney disease</p>	
<p>Drug Facts</p> <p>Active ingredient (in each tablet) Loratadine 10 mg.....Antihistamine</p> <p>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</p> <p>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.</p>	
<p>Drug Facts (continued)</p> <p>Other information ■ sealed with printed foil under cap for your protection ■ store at 20°-25°C (68°-77°F)</p> <p>Inactive ingredients lactose monohydrate, magnesium stearate, povidone, pregelatinized starch</p> <p>If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional.</p> <p>MANUFACTURED BY PEREGO ALBANY, MI 49010 USA</p>	

LOT NO.
0 000000 000000 0

EXP. AREA
27587 FA-05-1

Original Prescription Strength

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

24 Hour

Actual Size

Non-Drowsy* 300 days of relief

Loratadine Tablets, 10 mg

Antihistamine

Relief of:

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

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