

ALLERGY AND CONGESTION RELIEF- loratadine, pseudoephedrine sulfate tablet, film coated, extended release

L. Perrigo Company

Perrigo Allergy and Congestion Relief Drug Facts

Active ingredients (in each tablet)

Loratadine 5 mg

Pseudoephedrine sulfate 120 mg

Purpose

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - sneezing
 - itchy, watery eyes
 - runny nose
 - itching of the nose or throat
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

Warnings

Do not use

- if you have ever had an allergic reaction to this product or any of its ingredients
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- heart disease

- thyroid disease
- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland
- 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.
- symptoms do not improve within 7 days or are accompanied by a fever
- nervousness, dizziness or sleeplessness occurs

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 (1-800-222-1222).

Directions

- do not divide, crush, chew or dissolve the tablet

| | |
|--|--|
| adults and children 12 years and over | 1 tablet every 12 hours; not more than 2 tablets in 24 hours |
| children under 12 years of age | ask a doctor |
| consumers with liver or kidney disease | ask a doctor |

Other information

- **each tablet contains:** calcium 25 mg
- do not use if blister unit is broken or torn
- store between 20° to 25°C (68° to 77°F)
- keep in a dry place

Inactive ingredients

croscarmellose sodium, dibasic calcium phosphate, hypromellose, lactose monohydrate, magnesium stearate, pharmaceutical ink, povidone, titanium dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to Claritin-D[®] 12 hour Extended Release Tablets active ingredients
allergy & congestion relief

Pseudoephedrine Sulfate 120 mg/Loratadine 5 mg

Extended Release Tablets

Nasal Decongestant/Antihistamine

12 Hour

INDOOR & OUTDOOR ALLERGIES

Relief of:

Nasal and Sinus Congestion Due to Colds or Allergies

Sneezing - Runny Nose - Itchy, Watery Eyes

Itchy Throat or Nose Due to Allergies

Non-Drowsy*

*When taken as directed. See Drug Facts Panel.

Actual Size

20 EXTENDED RELEASE TABLETS

allergy & congestion relief

12 Hour

Compare to Claritin-D® 12 hour Extended Release Tablets active ingredients

NDC 0113-2007-60

allergy & congestion relief

Pseudoephedrine Sulfate 120 mg/Loratadine 5 mg
Extended Release Tablets
Nasal Decongestant/Antihistamine

12 Hour

INDOOR & OUTDOOR ALLERGIES

Relief of:

- Nasal and Sinus Congestion Due to Colds or Allergies
- Sneezing • Runny Nose • Itchy, Watery Eyes
- Itchy Throat or Nose Due to Allergies

Non-Drowsy*

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Actual Size



20 EXTENDED RELEASE TABLETS

7U060 55 C2

OPEN OTHER END

Drug Facts

| Active ingredients (in each tablet) | Purpose |
|-------------------------------------|--------------------|
| Loratadine 5 mg..... | Antihistamine |
| Pseudoephedrine sulfate 120 mg..... | Nasal decongestant |

Uses

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 - sneezing
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Ask a doctor before use if you have

- heart disease
- thyroid disease
- high blood pressure
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- trouble urinating due to an enlarged prostate gland
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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.
- symptoms do not improve within 7 days or are accompanied by a fever
- nervousness, dizziness or sleepiness occurs

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 (1-800-222-1222).

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Inactive ingredients croscarmellose sodium, dibasic calcium phosphate, hypromellose, lactose monohydrate, magnesium stearate, pharmaceutical ink, povidone, titanium dioxide

CONVENIENT RECLOSING TAB

Drug Facts (continued)

Questions or comments? 1-800-719-9260

Distributed By

Perrigo®

Allegan, MI 49010
perrigo.com



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ALLERGY AND CONGESTION RELIEF

loratadine, pseudoephedrine sulfate tablet, film coated, extended release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0113-2007 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------------|----------|
| LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN) | LORATADINE | 5 mg |
| PSEUDOEPHEDRINE SULFATE (UNII: Y9DL7QPE6B) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F) | PSEUDOEPHEDRINE SULFATE | 120 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|----------------------|---------------------|----------|
| Color | WHITE (to off-white) | Score | no score |
| Shape | ROUND | Size | 12mm |
| Flavor | | Imprint Code | 7U0 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0113-2007-46 | 10 in 1 CARTON | 04/17/2018 | 04/17/2018 |
| 1 | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:0113-2007-60 | 20 in 1 CARTON | 04/12/2018 | |
| 2 | | 1 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 | ANDA076050 | 04/12/2018 | |

Labeler - L. Perrigo Company (006013346)

Revised: 2/2024

L. Perrigo Company