ALLERGY CONGESTION RELIEF- loratadine, pseudoephedrine sulfate tablet, extended release Kroger Company

Kroger Co. Allergy & Congestion Relief Drug Facts

Active ingredients (in each tablet)

Loratadine 10 mg

Pseudoephedrine sulfate 240 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 daily with a full glass of water; not more than 1 tablet in 24 hours |
|--|---|
| children under 12 years of age | ask a doctor |
| consumers with liver or kidney disease | ask a doctor |

Other information

- do not use if printed blister unit is broken or torn
- store between 20° to 25°C (68° to 77°F)
- protect from light and store in a dry place

Inactive ingredients

colloidal silicon dioxide, ferric oxide, hydrogenated vegetable oil, hypromellose, magnesium stearate, polyethylene glycol, polyethylene oxide, propylene glycol, titanium dioxide

Questions or comments?

1-800-632-6900

Package/Label Principal Display Panel

COMPARE TO the active ingredients of CLARITIN-D® 24 HOUR

See bottom panel

 $Kroger_{\mathbb{R}}$

OUR PHARMACIST RECOMMENDED

Non-Drowsy*

Allergy & Congestion Relief

ACTUAL SIZE

RELIEF OF:

Nasal & Sinus

Congestion Due to Colds or Allergies;

Pseudoephedrine Sulfate 240 mg

Nasal Decongestant

Sneezing; Runny Nose; Itchy, Watery Eyes;

Itchy Throat or Nose Due to Allergies

Loratadine 10 mg

Antihistamine

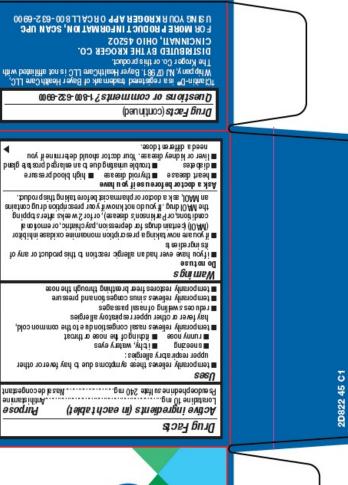
Extended Release Tablets

INDOOR & OUTDOOR ALLERGIES

24 HOUR

15 EXTENDED-RELEASE TABLETS

*When taken as directed. See Drug Facts Panel.





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Our Brands, Our Guarantee, Love It or Your Money Back.

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24hours

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consumers with live ror kidney dsease

12 years and over

adults and children

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Stop u se and ask a doctor if

Drug Facts(confined)

children under 12 years of age

Allergy & **Congestion Relief**



15 DAYS OF RELIEF

COMPARE TO the active ingredients of CLARITIN-D® 24 HOUR †See bottom panel



Non-Drowsy*

Allergy & **Congestion Relief**

Pseudoephedrine Sulfate 240 mg Nasal Decongestant Loratadine 10 mg Antihistamine **Extended Release Tablets INDOOR & OUTDOOR ALLERGIES**

*When taken as directed. See Drug Facts Panel.



RELIEF OF:

Nasal & Sinus Congestion Due to Colds or Allergies;

Sneezing; Runny Nose; Itchy, Watery Eyes; Itchy Throat or Nose **Due to Allergies**









ALLERGY CONGESTION RELIEF

loratadine, pseudoephedrine sulfate tablet, extended release

| Product | Inform | ation |
|----------------|--------|-------|
| I I Oddet | | acion |

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:30142-846 |
|--------------|----------------|--------------------|---------------|
|--------------|----------------|--------------------|---------------|

Route of Administration ORAL

| Active Ingredient/Active Moiety | | | |
|---|----------------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN) | LORATADINE | 10 mg | |
| PSEUDOEPHEDRINE SULFATE (UNII: Y9DL7QPE6B) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F) | PSEUDOEPHEDRINE SULFATE | 240 mg | |

| Inactive Ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | |

| Product Characteristics | | | |
|-------------------------|-------|--------------|----------|
| Color | WHITE | Score | no score |
| Shape | OVAL | Size | 19mm |
| Flavor | | Imprint Code | |
| Contains | | | |

| P | Packaging | | | | | |
|---|----------------------|--|-------------------------|-----------------------|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:30142-846- 22 | 15 in 1 CARTON | 02/22/2024 | | | |
| 1 | | 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 | ANDA075989 | 02/22/2024 | |
| | | | |

Labeler - Kroger Company (006999528)

Revised: 2/2024 Kroger Company