

HARRIS TEETER ALLERGY AND CONGESTION RELIEF- loratadine, pseudoephedrine sulfate tablet, film coated, extended release
Harris Teeter, LLC

Harris Teeter, LLC Allergy & 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

Allergy & Congestion Relief

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

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

INDOOR & OUTDOOR ALLERGIES

Non-Drowsy*

12 Hour

Relief of:

Nasal and Sinus Congestion Due to Colds or Allergies

Sneezing - Runny Nose - Itchy, Watery Eyes

Itchy Throat or Nose Due to Allergies

Actual Size

20 TABLETS

*When taken as directed. See Drug Facts Panel.

Allergy & Congestion Relief

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Loratadine 5 mg/Antihistamine
Extended Release Tablets**

INDOOR & OUTDOOR ALLERGIES

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Allergy & Congestion Relief

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7U0690 HT C2

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- heart disease
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Drug Facts (continued)

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Stop use and ask a doctor if

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- 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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CONVENIENT RECLOSING TAB

Drug Facts (continued)

Questions or comments? 1-800-719-9260

PROUDLY DISTRIBUTED BY:
HARRIS TEETER, LLC
MATTHEWS, NC 28105

your **plus** guarantee.

1-800-432-6111 or harristeeter.com

**This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Claritin-D® 12 hour Extended Release Tablets.



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HARRIS TEETER ALLERGY AND CONGESTION RELIEF

loratadine, pseudoephedrine sulfate tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69256-257
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	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:69256-257-60	20 in 1 CARTON	07/09/2018	
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	ANDA076050	07/09/2018	

Labeler - Harris Teeter, LLC (048463103)

