

TOPCARE ALLERGY AND CONGESTION RELIEF- loratadine, pseudoephedrine sulfate tablet, extended release
Topco Associates LLC

Topco Associates LLC. 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°-25°C (68°-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?

1-888-423-0139

Package/Label Principal Display Panel

TopCare® health

COMPARE TO CLARITIN-D® 24 HOUR EXTENDED RELEASE TABLETS

ACTIVE INGREDIENTS

NON-DROWSY*

Allergy & Congestion Relief

PSEUDOEPHEDRINE SULFATE 240 mg • LORATADINE 10 mg EXTENDED RELEASE TABLETS

NASAL DECONGESTANT • ANTIHISTAMINE

INDOOR & OUTDOOR ALLERGIES

24 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

15 EXTENDED RELEASE TABLETS

*When taken as directed. See Drug Facts Panel.

actual size

+TopCare®
health

NON-DROWSY*

24
HOUR

Allergy & Congestion Relief

PSEUDOEPHEDRINE SULFATE 240 mg • LORATADINE 10 mg EXTENDED RELEASE TABLETS
NASAL DECONGESTANT • ANTIHISTAMINE

INDOOR & OUTDOOR ALLERGIES

15 Days of Relief

*When taken as directed.
See Drug Facts Panel.

+TopCare®
health

NON-DROWSY*

Allergy & Congestion Relief

PSEUDOEPHEDRINE SULFATE 240 mg • LORATADINE 10 mg EXTENDED RELEASE TABLETS
NASAL DECONGESTANT • ANTIHISTAMINE

INDOOR & OUTDOOR ALLERGIES

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Drug Facts (continued)

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Drug Facts (continued)

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Distributed By
Perrigo®
Allergan, MI 49010
PERA0622



Scan here for more
information or
call 1-888-423-0139



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*This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Claritin-D® 24 hour Extended Release Tablets.

This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.



GLUTEN
FREE



TOPCARE ALLERGY AND CONGESTION RELIEF

loratadine, pseudoephedrine sulfate tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-706
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)	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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-706-22	15 in 1 CARTON	08/16/2023	
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	08/16/2023	

Revised: 8/2023

Topco Associates LLC