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

Topco Associates 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

	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?

1-888-423-0139

Package/Label Principal Display Panel

TopCare® health

COMPARE TO CLARITIN-D® 12 HOUR EXTENDED RELEASE TABLETS ACTIVE INGREDIENTS

NON-DROWSY*

Allergy & Congestion Relief

PSEUDOEPHEDRINE SULFATE 120 mg • LORATADINE 5 mg EXTENDED RELEASE TABLETS

NASAL DECONGESTANT • ANTIHISTAMINE

INDOOR & OUTDOOR ALLERGIES

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 30 EXTENDED RELEASE TABLETS
- *When taken as directed. See Drug Facts Panel. actual size

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Call 1-888-423-0139 intormation of

Scan here for more

Q nes flons or comments? 1-888-423-0130

Drug Facts (continued)

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Drug Facts

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Drug Facts (continued)

Stop use and ask a doctor if

When taken as directed. See Drug Facts Panel.

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is TopCare® product is laboratory sted to guarantee its highest quality. ur total satisfaction is guaranteed.

This product is not manufactured LLC, distributor of Claritin-D® 1

2 hour Extended

distributed by Bayer HealthCare nour Extended Release Tablets.



PSEUDOEPHEDRINE SULFATE 120 mg • LORATADINE 5 mg EXTENDED RELEASE TABLETS NASAL DECONGESTANT • ANTIHISTAMINE

INDOOR & OUTDOOR ALLERGIES



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

INDOOR & OUTDOOR ALLERGIES

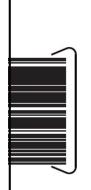


- Nasal and Sinus Congestion Due to Colds or Allergies
- Sneezing Runny Nose Itchy, Watery Eyes
- Itchy Throat or Nose Due to Allergies

EXTENDED RELEASE **TABLETS**

*When taken as directed. See Drug Facts Panel.

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TOPCARE ALLERGY AND CONGESTION RELIEF

loratadine, pseudoephedrine sulfate tablet, film coated, extended release

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-611

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN) PSEUDOEPHEDRINE SULFATE (UNII: Y9DL7QPE6B) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F) PSEUDOEPHEDRINE SULFATE (UNII: Y9DL7QPE6B) (PSEUDOEPHEDRINE - SULFATE) 120 mg

Inactive Ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)		
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

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

ı	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:36800-611- 65	30 in 1 CARTON	05/18/2018	
	L	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	05/18/2018	

Revised: 2/2022 Topco Associates LLC