

**SIGNATURE CARE ALLERGY AND CONGESTION RELIEF- loratadine, pseudoephedrine sulfate tablet, film coated, extended release Safeway**

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**Better Living Brands 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**

## Principal Display Panel

Compare to Claritin-D<sup>®</sup> 12 hour Extended Release Tablets active ingredients

Quality Guaranteed

12 HOUR | NON-DROWSY\*

Allergy & Congestion Relief

PSEUDOEPHEDRINE SULFATE 120 mg/LORATADINE 5 mg

EXTENDED RELEASE TABLETS

Nasal Decongestant/Antihistamine

Actual Size

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

\*When taken as directed. See Drug Facts Panel.

20 TABLETS

**OUR PROMISE**  
 100% QUALITY & SATISFACTION  
**GUARANTEED**  
 OR YOUR MONEY BACK.  
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 DISTRIBUTED BY  
 BETTER LIVING BRANDS LLC  
 HealthCare LLC, distributor of Clantm-D® 12 Hour Extended Release Tablets.  
 \*This product is not manufactured or distributed by Bayer.

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**Drug Facts (continued)**

**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) or certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease, or for 2 weeks after stopping an MAOI drug, if you do not know if your prescription drug contains heart disease, thyroid disease, or high blood pressure, ask a doctor before use if you have:
- diabetes
- heart or kidney disease. Your doctor should determine if you need a different dose.

**Use**

- 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 free breathing through the nose

**Active ingredients (in each tablet)**

Loratadine 5 mg, Pseudoephedrine sulfate 120 mg. Nasal decongestant.

**Purpose**

Antihistamine. Nasal decongestant.

**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.
- new rashes, 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).

**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°)
- keep in a dry place

**Inactive ingredients**

croscarmellose sodium, dibasic calcium phosphate, hypromellose, lactose monohydrate, magnesium stearate, povidone, titanium dioxide, hydroxypropyl methylcellulose, polyethylene glycol, polyethylene glycol 400, polyethylene glycol 600, polyethylene glycol 800, polyethylene glycol 1000, polyethylene glycol 1500, polyethylene glycol 2000, polyethylene glycol 4000, polyethylene glycol 6000, polyethylene glycol 8000, polyethylene glycol 10000, polyethylene glycol 15000, polyethylene glycol 20000, polyethylene glycol 40000, polyethylene glycol 60000, polyethylene glycol 80000, polyethylene glycol 100000, polyethylene glycol 150000, polyethylene glycol 200000, polyethylene glycol 400000, polyethylene glycol 600000, polyethylene glycol 800000, polyethylene glycol 1000000.

**Signature Care.**  
 Quality Guaranteed

**12 HOUR | NON-DROWSY\***  
**Allergy & Congestion Relief**  
 PSEUDOEPHEDRINE SULFATE 120 mg/LORATADINE 5 mg  
 EXTENDED RELEASE TABLETS  
 Nasal Decongestant/Antihistamine  
 \*When taken as directed. See Drug Facts Panel.

**Signature Care.**  
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**12 HOUR | NON-DROWSY\***  
**Allergy & Congestion Relief**  
 PSEUDOEPHEDRINE SULFATE 120 mg/LORATADINE 5 mg  
 EXTENDED RELEASE TABLETS  
 Nasal Decongestant/Antihistamine  
 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

\*When taken as directed. See Drug Facts Panel.

Compare to Claritin-D® 12 hour Extended Release Tablets active ingredients\*\*  
 NDC 21130-482-60

Actual Size  
  
**20 TABLETS**

7U060 L1 C4

# SIGNATURE CARE ALLERGY AND CONGESTION RELIEF

loratadine, pseudoephedrine sulfate tablet, film coated, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:21130-482
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

## Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-482-60	20 in 1 CARTON	04/02/2018	
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	04/02/2018	

