

**CAREONE ALLERGY AND CONGESTION RELIEF- loratadine, pseudoephedrine sulfate tablet, film coated, extended release**  
**American Sales Company**

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**American Sales Company 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**

Compare to the active ingredients in Claritin-D® 12 hour  
12hr

12 HOUR – Non-Drowsy\*

Allergy & Congestion Relief

Pseudoephedrine Sulfate 120 mg/Nasal Decongestant

Loratadine 5 mg/Antihistamine

Extended Release Tablets

Actual Size

30 EXTENDED RELEASE TABLETS

INDOOR & OUTDOOR ALLERGIES

12 HOUR RELIEF OF:

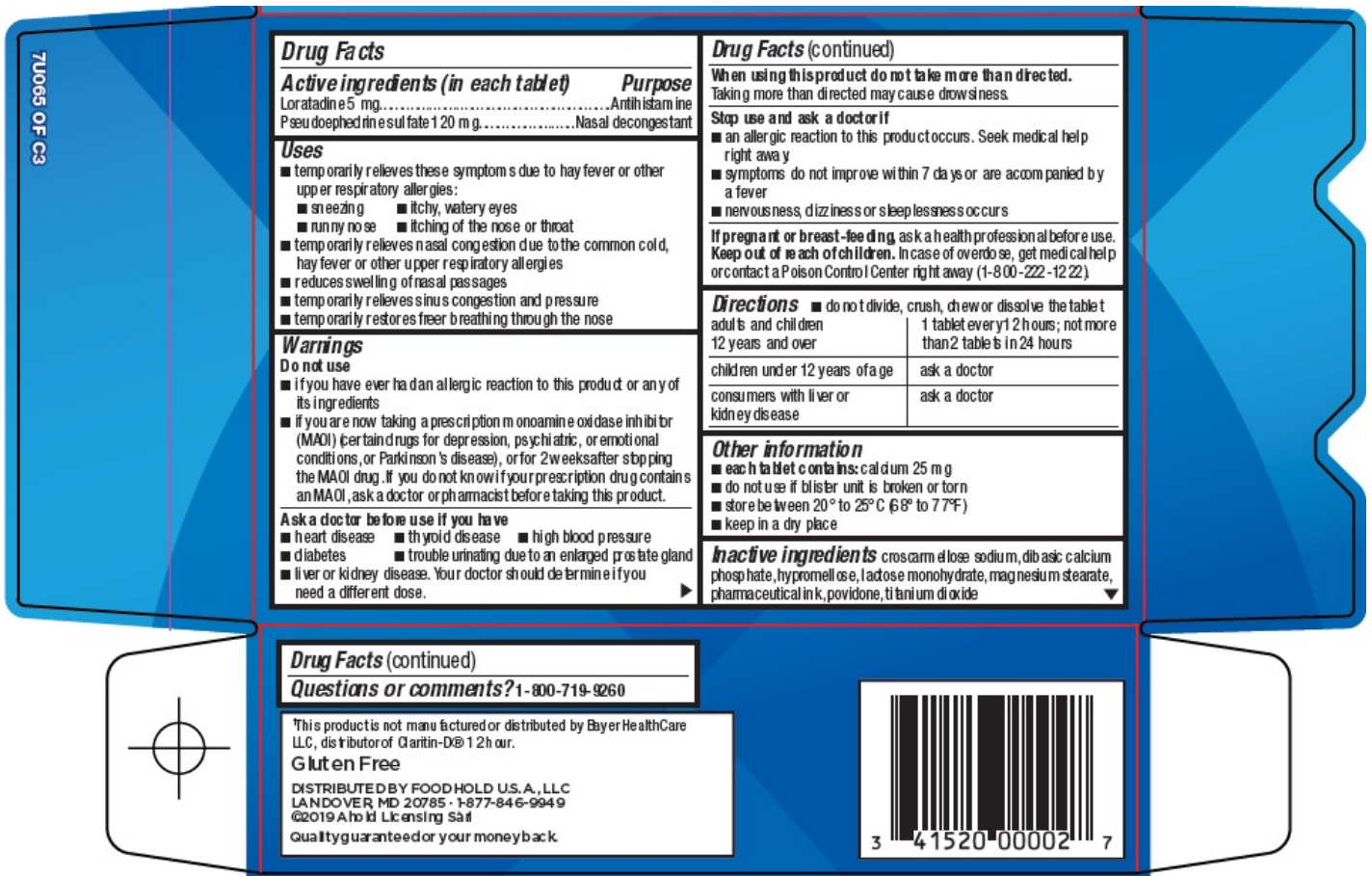
Nasal and Sinus Congestion Due to Colds or Allergies

Sneezing – Runny Nose – Itchy, Watery Eyes - Itchy Throat or Nose Due to Allergies

OUR PHARMACISTS RECOMMEND

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





## CAREONE 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:41520-918 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength       | Strength |
|---|-------------------------|----------|
| LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII: 7AJ03BO7QN)                   | LORATADINE              | 5 mg     |
| PSEUDOEPHEDRINE SULFATE (UNII: Y9DL7QPE6B) (PSEUDOEPHEDRINE - UNII: 7CUC9DDI9F) | 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: FZ989GH94E)               |          |
| TITANIUM DIOXIDE (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:41520-918-65 | 30 in 1 CARTON   | 03/07/2019           |                    |
| 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                               | 03/07/2019           |                    |

**Labeler** - American Sales Company (809183973)

Revised: 10/2020

American Sales Company