

**ALAVERT ALLERGY AND CONGESTION D-12 HOUR- loratadine and pseudoephedrine sulfate tablet, film coated, extended release
Foundation Consumer Brands**

**Alavert®
Allergy and Congestion D-12 hour**

Drug Facts

Active ingredients (in each tablet)	Purposes
Loratadine 5 mg	Antihistamine
Pseudoephedrine sulfate 120 mg	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
- 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?

Call **1-800 ALAVERT (1-800-252-8378)** weekdays 9 AM to 5 PM EST

Distributed by: Foundation Consumer Brands, LLC
Pittsburgh, PA 15212

PRINCIPAL DISPLAY PANEL - 24 Tablet Blister Pack Carton

Compare ours to the Active Ingredients in
Claritin-D® 12 Hour Tablets†

allergy & congestion

ALAVERT®
D-12

HOUR

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

Non-Drowsy*

Relief of:

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

Indoor & Outdoor Allergies

*When taken as directed. See Drug Facts Panel.

24 TABLETS

Actual Size



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alavert.com



Drug Facts (continued)

Active ingredients (in each tablet)

Uses

- temporarily relieves the symptoms due to hay fever or other upper respiratory allergic reactions such as 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
- relieves swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily relieves the breathing through the nose

Warnings

- Do not use
- if you have ever had an allergic reaction to this product or any of 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
 - trouble urinating due to an enlarged prostate gland
 - high blood pressure
- your doctor should determine if you need a different dose.

Questions or comments?

Call 1-800-ALAVERT (1-800-252-8378) weekdays 9AM to 5PM EST

allergy & congestion
ALAVERT® D-12 HOUR

7Z262 MJ C1

"This product is not manufactured by Bayer HealthCare LLC, the distributor of Claritin-D 12 Hour Tablets."

allergy & congestion
ALAVERT® D-12 HOUR
Pseudoephedrine Sulfate 120mg/Nasal Decongestant Loratadine 5mg/Antihistamine - Extended Release Tablets
Non-Drowsy*

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allergy & congestion

ALAVERT® D-12 HOUR

Pseudoephedrine Sulfate 120 mg/Nasal Decongestant
Loratadine 5 mg/Antihistamine - Extended Release Tablets
Non-Drowsy*

24 Tablets

EACH TABLET IS BLISTER SEALED. DO NOT USE IF SEAL IS BROKEN.

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7Z262MJ C1

allergy & congestion

ALAVERT® D-12 HOUR

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Loratadine 5 mg/Antihistamine - Extended Release Tablets
Non-Drowsy*

Relief of:

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

*When taken as directed. See Drug Facts Panel.

Actual Size

24 TABLETS

7Z262MJ C1

ALAVERT ALLERGY AND CONGESTION D-12 HOUR

loratadine and pseudoephedrine sulfate tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80070-100
Route of Administration	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

Color	WHITE (white to off-white)	Score	no score
Shape	ROUND (extra deep convex)	Size	14mm
Flavor		Imprint Code	7U0
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80070-100-12	2 in 1 CARTON	12/15/2021	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:80070-100-24	4 in 1 CARTON	12/15/2021	
2		6 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	12/15/2021	

Labeler - Foundation Consumer Brands (117603632)

Revised: 12/2021

Foundation Consumer Brands