

**ALAVERT ALLERGY SINUS D-12- loratadine, pseudoephedrine sulfate tablet,
film coated, extended release
Haleon US Holdings LLC**

Drug Facts

ACTIVE INGREDIENTS (IN EACH TABLET)

Loratadine 5 mg

Pseudoephedrine sulfate 120 mg

PURPOSES

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 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° and 25°C (68° and 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 weekdays from 9 AM to 5 PM EST at **1-800-ALAVERT (1-800-252-8378)**

Distributed by: Pfizer, Madison, NJ 07940 USA

PRINCIPAL DISPLAY PANEL

NDC 0573-2660-24

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

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

24 TABLETS

Actual Size

*When taken as directed.

See Drug Facts Panel.

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100% For Position Only

Distributed by: Pfizer, Inc., Madison, NJ 07940 USA
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For most recent product information, visit www.alavert.com

Drug Facts (continued)
Inactive ingredients: croscarmellose sodium, dibasic calcium phosphate, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, polyethylene glycol, titanium dioxide
Questions or comments? Call weekdays from 9 AM to 5 PM EST at 1-800-ALAVERT (1-800-252-8378)

Drug Facts (continued)
Purposes
Antihistamine
Nasal decongestant
Active ingredients (in each tablet)
Loratadine 5 mg
Pseudoephedrine sulfate 120 mg
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 free breathing through the nose
Warnings
Do not use
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if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, Parkinson's disease, or emotional conditions, 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
diabetes
trouble urinating due to an enlarged prostate gland
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
Directions
do not divide, crush, chew or dissolve the tablet
adults and children 12 years and over
not more than 2 tablets in 24 hours
ask a doctor
children under 12 years of age
ask a doctor
consumers with liver or kidney disease
ask a doctor
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
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allergy & congestion

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

ALAVERT® D-12
HOUR

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

24 Tablets

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Claritin-D® 12 Hour Tablets†

allergy & congestion

ALAVERT®

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

Non-Drowsy*

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

Indoor & Outdoor Allergies

D-12
HOUR

24 TABLETS

Actual Size

*When taken as directed.
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allergy & congestion

ALAVERT[®] D-12

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Pseudoephedrine Sulfate 120mg/Neer Decongestant
Loratadine 5mg/Antihistamine — Extended Release Tablets

Non-Drowsy*

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allergy & congestion

ALAVERT[®] D-12

HOURLY

CODE AREA

7Z262 6Z C1



ALAVERT ALLERGY SINUS D-12

loratadine, pseudoephedrine sulfate tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-2660
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: 70097M6I3O)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (white to off-white)	Score	no score
Shape	ROUND (round shape and an extra deep convex)	Size	14mm
Flavor		Imprint Code	Alavert;D12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-2660-12	2 in 1 CARTON	01/30/2004	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0573-2660-24	4 in 1 CARTON	01/30/2004	
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	01/30/2004	

Labeler - Haleon US Holdings LLC (079944263)

Revised: 2/2024

Haleon US Holdings LLC