

ALAVERT ALLERGY SINUS D-12- loratadine, pseudoephedrine sulfate tablet, film coated, extended release

Wyeth Consumer Healthcare LLC

ALAVERT® ALLERGY SINUS D-12

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 - 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

†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.

3 0573 2660 24 0

100% For Position Only



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

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 EST at 1-800-ALAVERT (1-800-252-8378)

Inactive ingredients croscarmellose sodium, dibasic calcium phosphate, hypromellose, lactose monohydrate, magnesium stearate, pharmaceutical ink, povidone, titanium dioxide

Drug Facts (continued)

Drug Facts (continued)

■ 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.

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

Drug Facts

Active ingredients (in each tablet)

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 ■ itching, 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
- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

Warnings

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- 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

Do not use

- if you have ever had an allergic reaction to this product or any of its ingredients

allergy & congestion

ALAVERT® D-12

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

Non-Drowsy*

24 Tablets

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

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

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

allergy & congestion

ALAVERT®

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

D-12 HOUR

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



Actual Size

24 TABLETS

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

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



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allergy & congestion

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

Non-Drowsy*

allergy & congestion

ALAVEI

CODE A

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: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	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 (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
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ANDA	ANDA076050	01/30/2004	
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Labeler - Wyeth Consumer Healthcare LLC (828831730)

Revised: 12/2018

Wyeth Consumer Healthcare LLC