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	1 tablet every 12 hours; not more
years and over	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.

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For most recent product information, visit www.alavert.com © 2018 Pfizer Inc.

Distributed by: Pfizer, Madison, NJ 07940 USA

EST at 1-800-ALAVERT (1-800-252-8378) Questions or comments? Call weekdays from 9 AM to 5 PM

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Pseudoephedrine sulfate 1 20 mgpm OS is alfatine aniheadaobues Loratadine 5 mg enimstahltnA.. səsodın_d

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Drug Facts

24 Tablets

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■ store between 20° to 25°C (68° to 77°F)

do not use if bilster unit is broken or torn

■ each tablet contains: calcium 25 mg

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sak a doctor	children under 12 years of age
1 tablet every 12 hours, not more than 2 tablets in 24 hours	12 years and over

do not divide, crush, chew or dissolve the tablet

Directions

contact a Poison Control Center right away (1-800-222-1222). Keep out of reach of children. In case of overdose, get medical help or If pregnant or breast-feeding, ask a health professional before use.

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allergy & congestion

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

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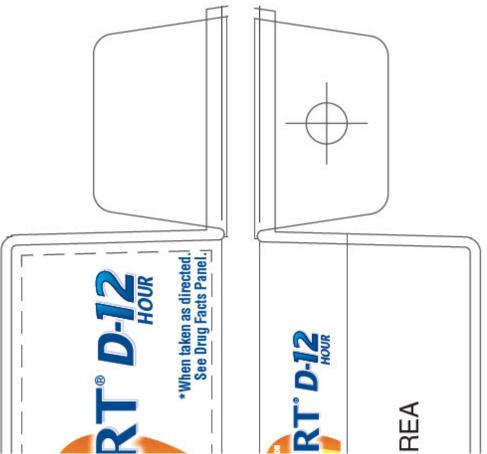
Pseudoephedrine Sulfate 120 mg/Nasal Decongestant Loratadine 5 mg/Antihistamine — Extended Release Tablets

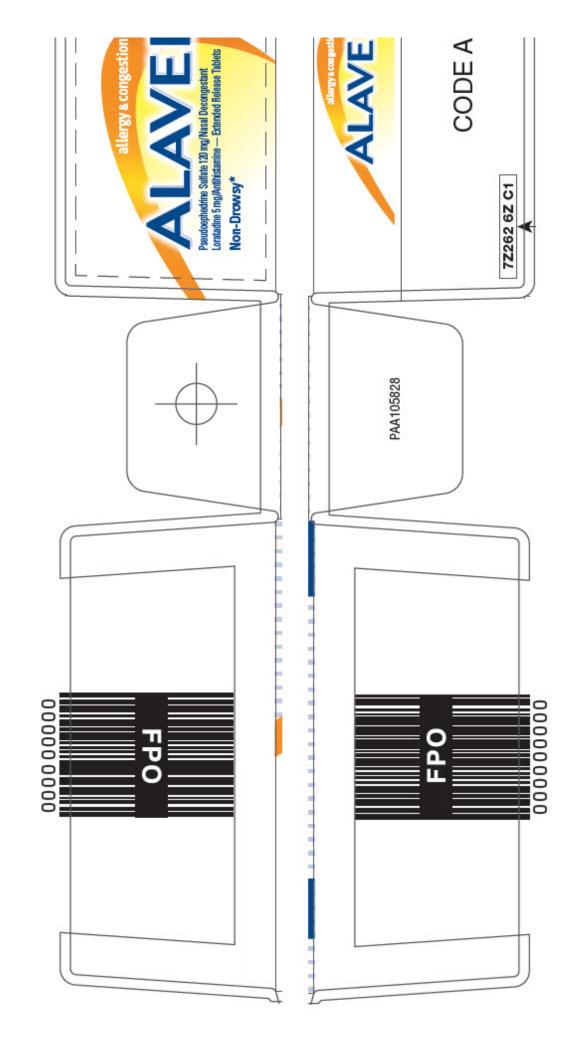
Non-Drowsy*

*When taken as directed. See Drug Facts Panel

Compare ours to the Active Ingredients in







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		
PSEUDO EPHEDRINE SULFATE (UNII: Y9 DL7QPE6B) (PSEUDO EPHEDRINE - UNII:7CUC9 DDI9F)	PSEUDOEPHEDRINE SULFATE	120 mg		

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)			
ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

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				

P	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 $1BLISTERPACK;Type0\colon Nota$ Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	

ANDA ANDA076050 01/30/2004

Labeler - Wyeth Consumer Healthcare LLC (828831730)

Revised: 12/2018 Wyeth Consumer Healthcare LLC