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 $^{\circledR}$ 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



Distributed by:Foundation Consumer Brands, LLC Pittsbr.rdp.hA1,5212 ©2020 al avert.com



1This product is not manufactured by Bayer HealthCare LLC, the distributor of Claritin-D® 12 Hour Tablets.

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Drug Facts

ALAVERT D-12

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allergy & congestion

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



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

24 Tablets

*When taken as directed. See Drug Facts Panel.

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

allergy & congestion

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

Non-Drowsy* Relief of:

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Indoor & Outdoor Allergies

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D-12 HOUR

24 TABLETS

Actual Size



120220



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: 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: FZ 989GH94E)			
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			

P	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