ALLERGY AND CONGESTION RELIEF NON DROWSY- pseudoephedrine sulfate, loratadine tablet, film coated HyVee Inc

Hy-Vee, Inc. Allergy & Congestion Relief Drug Facts

Active ingredient (in each tablet)

Loratadine 10 mg

Pseudoephedrine sulfate 240 mg

Purpose

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 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.

Directions

• do not divide, crush, chew or dissolve the tablet

adults and children 12 years and	1 tablet daily with a full glass of water; not
over	more than 1 tablet in 24 hours
children under 12 years of age	ask a doctor
consumers with liver or kidney	ask a doctor
disease	

Other information

- store between 20°C to 25°C (68°F to 77°F)
- protect from light and store in a dry place

Inactive ingredients

colloidal silicon dioxide, hydrogenated vegetable oil, hypromellose, magnesium stearate, pharmaceutical ink, polyethylene glycol, polyethylene oxide, titanium dioxide

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Non-Drowsy

Compare to Claritin-D® 24 Hour active ingredients

Allergy & Congestion Relief

Pseudoephedrine Sulfate 240 mg/Nasal Decongestant

Loratadine 10 mg/Antihistamine

Extended Release Tablets

24 hour

Relief of:

Nasal and Sinus Congestion Due to Colds or Allergies

Sneezing

Runny Nose

Itchy, Watery Eyes

Itchy Throat or Nose Due to Allergies

Actual Size

Original Prescription Strength

*When taken as directed. See Drug Facts Panel.



Allergy & Congestion Relief Carton Image 1



Allergy & Congestion Relief Carton Image 2

ALLERGY AND CONGESTION RELIEF NON DROWSY

pseudoephedrine sulfate, loratadine tablet, film coated

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:42507-724 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	10 mg	
PSEUDO EPHEDRINE SULFATE (UNII: Y9DL7QPE6B) (PSEUDO EPHEDRINE - UNII:7CUC9DD19F)	PSEUDOEPHEDRINE SULFATE	240 mg	

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	

Product Characteristics			
Color	WHITE (Off-White)	Score	no score
Shape	OVAL	Size	18 mm
Flavor		Imprint Code	L724
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:42507-724-22	3 in 1 CARTON			
1		5 in 1 BLISTER PACK			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075989	10/26/2010	

Labeler - HyVee Inc (006925671)

Revised: 1/2011 HyVee Inc