ALLERGY RELIEF-D 24 HOUR 24 HOUR- loratadine and pseudoephedrine sulfate tablet, extended release
Actavis Pharma, Inc.

Loratadine and Pseudoephedrine Sulfate Extended-Release Tablets

Drug Facts

Active ingredients (in each tablet)

Loratadine, USP 10 mg
Pseudoephedrine sulfate, USP 240 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 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 over	1 tablet daily with a full glass of water; not more than 1 tablet in 24 hours
children under 12 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- safety sealed: do not use if blister unit is open or torn
- store between 20° to 25°C (68° to 77°F)
- protect from light and store in a dry place

Inactive ingredients

black iron oxide, candelilla wax powder, colloidal silicon dioxide, glyceryl monostearate, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, polysorbate 80, propylene glycol, sodium lauryl sulfate, talc and titanium dioxide

Questions?

1-888-838-2872 between 9 am and 5 pm ET, Monday – Friday.

Principal Display Panel

Actavis™

NDC 52544-**239**-12
Compare to the active ingredients in Claritin-D® 24 Hour†

Non-Drowsy*
Allergy Relief-D
Loratadine, USP 10 mg/Pseudoephedrine Sulfate, USP 240 mg
Extended-Release Tablets
Antihistamine/Nasal Decongestant

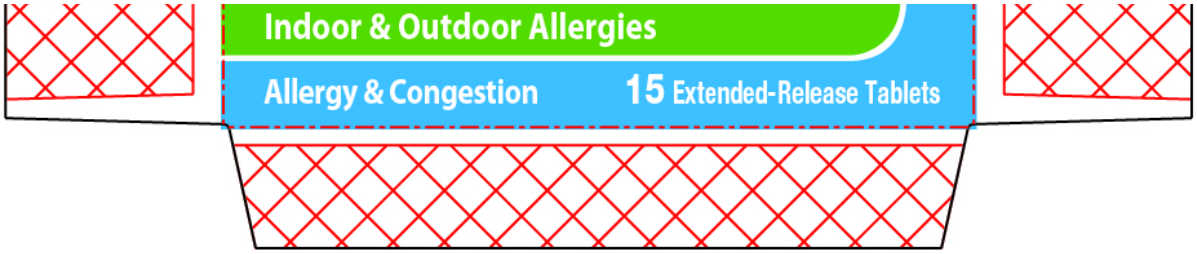
24 Hour Relief of:

- Nasal & Sinus Congestion Due to Colds or Allergies
- Sneezing
- Runny Nose
- Itchy, Watery Eyes

- Itchy Throat or Nose Due to Allergies

*When taken as directed. See Drug Facts Panel.

Indoor & Outdoor Allergies
Allergy & Congestion
15 Extended-Release Tablets



ALLERGY RELIEF-D 24 HOUR 24 HOUR

loratadine and pseudoephedrine sulfate tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52544-239
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	10 mg
PSEUDOEPHEDRINE SULFATE (UNII: Y9DL7QPE6B) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE SULFATE	240 mg

Inactive Ingredients

Ingredient Name	Strength
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
CANDELILLA WAX (UNII: WL0328HX19)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	OVAL	**Size**	18mm

Flavor		**Imprint Code**	Andrx;605
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52544-239-12	3 in 1 CARTON	06/14/2018	
1		5 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	ANDA075706	06/14/2018	

Labeler - Actavis Pharma, Inc. (119723554)

Revised: 2/2018 Actavis Pharma, Inc.