

CLARITIN-D 24 HOUR- loratadine pseudoephedrine sulfate tablet, extended release

Bayer HealthCare LLC.

Claritin-D®

24 Hour

Drug Facts

<i>Active ingredient (in each tablet)</i>	<i>Purpose</i>
Loratadine 10 mg	Antihistamine
Pseudoephedrine sulfate 240 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.

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

- 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, Inactive ingredients colloidal silicon dioxide, glyceryl monostearate, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, polysorbate 80, propylene glycol, sodium lauryl sulfate, talc, titanium dioxide

Questions or comments?

1-800-CLARITIN (1-800-252-7484) or www.claritin.com

PRINCIPAL DISPLAY PANEL - 10 Tablet Blister Pack Carton



Non-Drowsy*

Claritin-D®

pseudoephedrine sulfate 240 mg/nasal decongestant

loratadine 10 mg/antihistamine

Indoor & Outdoor Allergies

Allergy & Congestion

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.**

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EXTENDED

RELEASE TABLETS

CLARITIN-D 24 HOUR

loratadine pseudoephedrine sulfate tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11523-0102
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
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
TALC (UNII: 7SEV7J4R1U)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CANDELILLA WAX (UNII: WL0328HX19)	

HYPROMELLOSES (UNII: 3NXW29V3WO)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (white to off-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:11523-0102-1	1 in 1 CARTON	12/12/2022	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11523-0102-2	1 in 1 CARTON	12/12/2022	
2		15 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	12/12/2022	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 11/2023

Bayer HealthCare LLC.