CLARITIN-D 12 HOUR- loratadine and pseudoephedrine sulfate tablet, extended release
Bayer HealthCare LLC.

Claritin-D ®

12 Hour

Drug Facts

Active ingredient (in each tablet)	***Purpose***
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.

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 30 mg
- safety sealed: do not use if the individual blister unit imprinted with Claritin-D ® 12 Hour is open or torn
- 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 sterarate, pharmaceutical ink, povidone, titanium dioxide

Questions or comments?

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

PRINCIPAL DISPLAY PANEL - Carton

NDC 11523-7162-1

Non-Drowsy*

Claritin-D®

pseudoephedrine sulfate 120 mg/nasal decongestant

loratadine 5 mg/antihistamine

Indoor & Outdoor Allergies

Allergy & Congestion

12

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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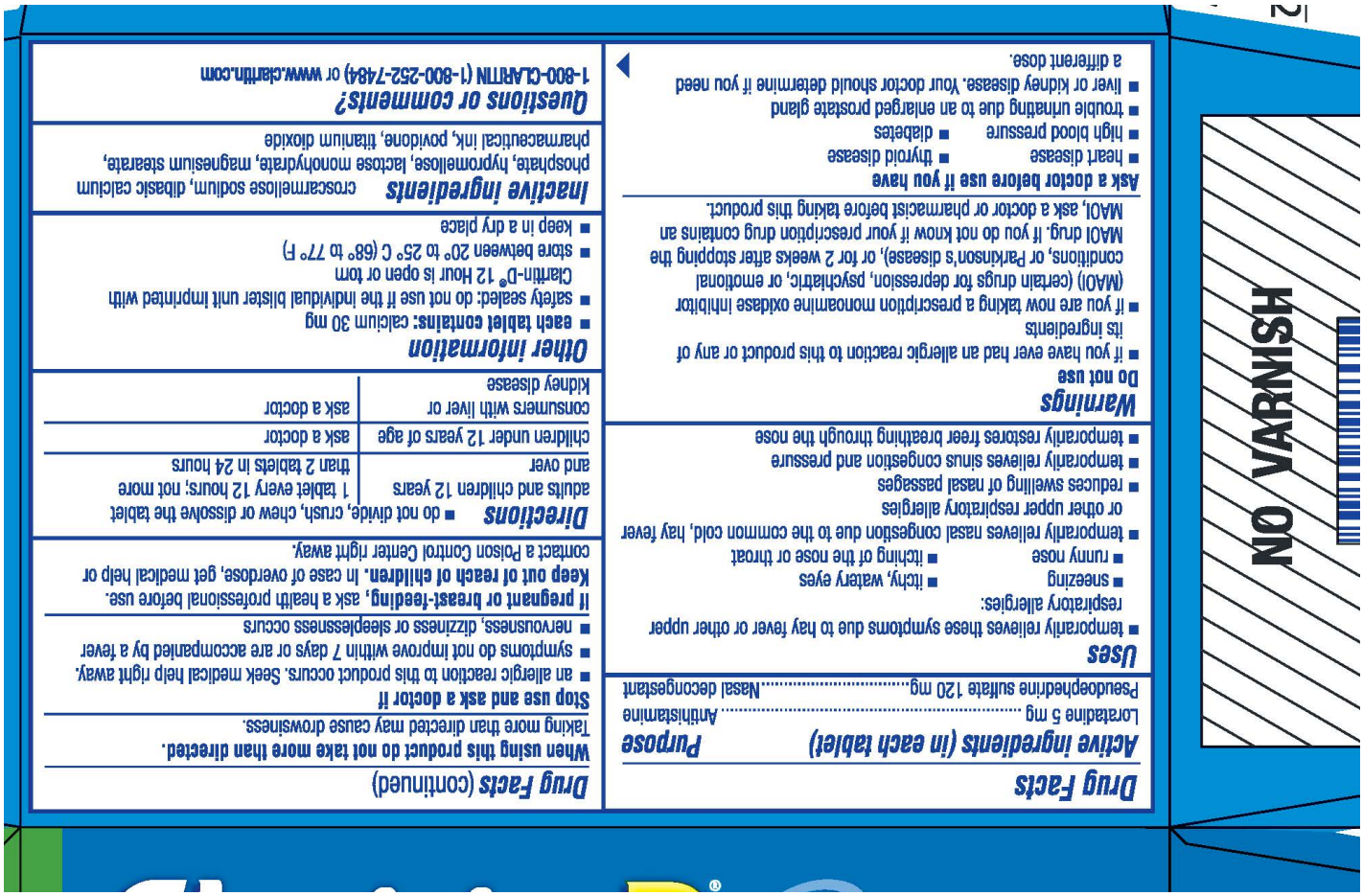
EXTENDED

RELEASE TABLETS





CLARITIN-D 12 HOUR

loratadine and pseudoephedrine sulfate tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11523-7162
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)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (white to off-white)	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	Claritin;D;12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11523-7162-1	1 in 1 CARTON	12/01/2009	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11523-7162-2	2 in 1 CARTON	12/01/2009	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:11523-7162-3	3 in 1 CARTON	12/01/2009	
3		10 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
NDA	NDA019670	12/01/2009	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 12/2025 Bayer HealthCare LLC.