

**CLARITIN-D 12 HOUR- loratadine and pseudoephedrine sulfate tablet,
extended release
REMEDYREPACK INC.**

Claritin-D ®

12 Hour

Drug Facts

<i>Active ingredient (in each tablet)</i>	<i>Purpose</i>
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 stearate, pharmaceutical ink, povidone, titanium dioxide

Questions or comments?

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

DRUG: Claritin-D12 Hour 12 Hour

GENERIC: Loratadine and pseudoephedrine sulfate

DOSAGE: TABLET, EXTENDED RELEASE

ADMINISTRATION: ORAL

NDC: 70518-3566-0

COLOR: white

SHAPE: OVAL

SCORE: No score

SIZE: 12 mm

IMPRINT: Claritin;D;12

PACKAGING: 10 in 1 BLISTER PACK

OUTER PACKAGING: 2 in 1 CARTON

ACTIVE INGREDIENT(S):

- PSEUDOEPHEDRINE SULFATE 120mg in 1
- LORATADINE 5mg in 1

INACTIVE INGREDIENT(S):

- CROSCARMELLOSE SODIUM
- CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS
- HYPROMELLOSES
- LACTOSE MONOHYDRATE
- MAGNESIUM STEARATE
- POVIDONE
- TITANIUM DIOXIDE

Claritin-D

Pseudoephedrine / Loratadine
Extended - Release

120mg / 5 mg

Tablet

QTY: 20 Tablets



NOT FOR RETAIL SALE

NDC #: 70518-3566-00

Expires:

LOT #:

Source NDC: 11523-7162-02

MFG: Bayer Healthcare, Whippany, NJ 07981

Keep this and all medication out of the reach of children



Directions For Use: See Package Insert

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [See USP]

Repackaged by: RemedyRepack Inc., Indiana, PA 15701, 724.465.8762

CLARITIN-D 12 HOUR

loratadine and pseudoephedrine sulfate tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70518-3566(NDC:11523-7162)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII:7AJ03BO7QN)	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: 70097M6I3O)				
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:70518-3566-0	2 in 1 CARTON	10/31/2022	
1		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	10/31/2022	

Labeler - REMEDYREPACK INC. (829572556)

Revised: 11/2022

REMEDYREPACK INC.