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

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Claritin-D ®

12 Hour

Drug Facts

<table>
<thead>
<tr>
<th>Active ingredient (in each tablet)</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loratadine 5 mg</td>
<td>Antihistamine</td>
</tr>
<tr>
<td>Pseudoephedrine sulfate 120 mg</td>
<td>Nasal decongestant</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Adults and children 12 years and over</th>
<th>1 tablet every 12 hours; not more than 2 tablets in 24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children under 12 years of age</td>
<td>ask a doctor</td>
</tr>
<tr>
<td>Consumers with liver or kidney disease</td>
<td>ask a doctor</td>
</tr>
</tbody>
</table>

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

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.
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

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)</td>
<td>LORATADINE</td>
<td>5 mg</td>
</tr>
<tr>
<td>PSEU DOE PHE DR I N E SULFATE (UNII: Y9DL7QPE6B) (PSEU DOE PHE DR I N E - UNII:7CUC9DDDBF)</td>
<td>PSEU DOE PHE DR I N E SULFATE</td>
<td>120 mg</td>
</tr>
</tbody>
</table>

Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)</td>
<td></td>
</tr>
<tr>
<td>CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)</td>
<td></td>
</tr>
<tr>
<td>HYPRO MELLOSES (UNII: 3NXW29V3WO)</td>
<td></td>
</tr>
<tr>
<td>LACTOSE MONOHYDRATE (UNII: EWQ57Q815X)</td>
<td></td>
</tr>
<tr>
<td>MAGNESIUM STEARATE (UNII: 70097M6D30)</td>
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</tr>
</tbody>
</table>
**Product Characteristics**

<table>
<thead>
<tr>
<th>Color</th>
<th>Score</th>
<th>Shape</th>
<th>Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>white (white to off-white)</td>
<td>no score</td>
<td>OVAL</td>
<td>12mm</td>
</tr>
</tbody>
</table>

**Flavor**

- Imprint Code: Claritin;D;12

**Packaging**

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tbody>
<tr>
<td>1</td>
<td>NDC:11523-7162-1</td>
<td>1 in 1 CARTON</td>
<td>12/01/2009</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>10 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
<td></td>
<td></td>
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<tr>
<td>2</td>
<td>NDC:11523-7162-2</td>
<td>2 in 1 CARTON</td>
<td>12/01/2009</td>
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<tr>
<td>2</td>
<td></td>
<td>10 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
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<tr>
<td>3</td>
<td>NDC:11523-7162-3</td>
<td>3 in 1 CARTON</td>
<td>12/01/2009</td>
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<tr>
<td>3</td>
<td></td>
<td>10 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
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**Marketing Information**

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<tr>
<td>NDA</td>
<td>NDA019670</td>
<td>12/01/2009</td>
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**Labeler** - Bayer HealthCare LLC. (112117283)

Revised: 11/2019