

Clarityn-D® 24 Hour Extended Release

401362/05



Brand of loratadine and pseudoephedrine sulfate
Extended-Release, Non-Sedating Antihistamine / Decongestant Tablets

Product Description

Each Clarityn-D® 24 Hour Extended Release Tablet contains 10 mg loratadine in the tablet coating and 240 mg pseudoephedrine sulfate in the tablet core. The loratadine component is released immediately, whereas the pseudoephedrine component is released slowly from the core allowing for once daily dosing.

Also contains: Hydroxypropyl Methylcellulose, Ethylcellulose, Calcium Hydrogen Phosphate, Polyvidone, Silicon Dioxide, Magnesium Stearate, Hydroxypropyl Methylcellulose, Polyethylene Glycol, White Color Dispersion and Macrogol 400.

Clarityn-D® 24 Hour Extended Release is available in blister packs of 10 tablets.

What is Clarityn-D® 24 Hour Extended Release and what is it used for?

Clarityn-D® 24 Hour Extended Release relieves symptoms associated with allergic rhinitis and the common cold, including

- nasal congestion
- sneezing
- runny, itchy nose,
- watery, itchy eyes

Clarityn-D® 24 Hour Tablets Extended Release Tablet contains a combination of two medicines, loratadine (an antihistamine) and pseudoephedrine (a decongestant).

Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine. Histamine is produced by the body in response to foreign substances which the body is allergic to. Decongestants clear stuffy or blocked nose.

How to take Clarityn-D® 24 Hour Extended Release?

The recommended dose for Clarityn-D® 24 Hour Extended Release in adults and children over 12 years is one tablet once daily. It does not matter if you take Clarityn-D® 24 Hour Extended Release before or after food.

Swallow the tablet whole with a glass of water. Do not crush, break or chew the tablet before swallowing.

If you have severe liver problems, your pharmacist or doctor may advise you to take one tablet on alternate day with a glass of water, with or without food.

Be sure to take Clarityn-D® 24 Hour Extended Release exactly as your doctor or pharmacist has told you to. If you do not follow their instructions, you may not get relief from your symptoms.

When should Clarityn-D® 24 Hour Extended Release not be taken?

Do not take Clarityn-D® 24 Hour Extended Release if:

- you are allergic to loratadine, pseudoephedrine or any of its other ingredients
- you are on monoamine oxidase inhibitors, medicines used to treat depression, or within two weeks of discontinuing such treatment
- with narrow angle glaucoma
- with urinary retention
- with severe high blood pressure
- with severe coronary artery disease (heart disease)
- who have hyperthyroidism (overactive thyroid gland)
- you have a history of difficulty in swallowing tablets, or have had known upper gastrointestinal narrowing or abnormal esophageal peristalsis

Do not give this medicine to a child under the age of 12 years.

Pregnancy and breast-feeding

Safe use of Clarityn-D® 24 Hour Extended Release during pregnancy has not been established. Therefore, the product should be used only if the potential benefit justifies the potential risk to the fetus.

Since loratadine and pseudoephedrine sulfate are excreted in breast milk, a decision should be made whether to discontinue nursing or to discontinue the use of this product. Please speak to your doctor or pharmacist if you are breastfeeding and intend to take Clarityn-D® 24 Hour Extended Release Tablet.

What are the precautionary measures to be observed when taking Clarityn-D® 24 Hour Extended Release?

Clarityn-D® 24 Hour Extended Release should be used with caution in patients with

- glaucoma
- prostate or urinary bladder problems
- heart disease
- diabetes
- 60 years of age or older, because older adults maybe more sensitive to the effects of the medicines
- liver disease
- stomach ulcer
- intestinal obstruction

Laboratory tests

If you are scheduled to have any skin tests for allergies, you should not take Clarityn-D® 24 Hour Extended Release for two days before.

Acute generalized exanthematous pustulosis (AGEP), a form of severe skin reaction, may occur in isolated cases. If you have signs and symptoms such as fever, redness, or small (generalized) pustules, you should stop taking Clarityn-D® 24Hour Extended Release and consult your doctor.

Possible side effects

Like all medicines, Clarityn-D® 24 Hour Extended Release can cause side effects, although not everybody gets them. The most commonly reported side effects include headache and dry mouth. Less commonly reported events were drowsiness and inability to sleep. Rarely reported side effects include dizziness, fatigue, lack of appetite for food, nervousness, nausea, nosebleed, runny nose, tear gland disorder, lack of strength, muscle spasm, constipation, indigestion, palpitation, rapid heart rate, thirst, agitation, irritability, coughing, shortness of breath, nasal irritation, and sore throat. Isolated cases of acute generalized exanthematous pustulosis (AGEP), a form of skin reaction, have also been reported with pseudoephedrine-containing products.

If you experience any of these side effects or you notice any not listed in this leaflet, stop taking the medicine and contact your pharmacist or doctor at once.

What other medicine should be avoided whilst taking Clarityn-D® 24 Hour Extended Release?

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that are obtained without a prescription. Some medicines should not be taken with Clarityn-D® 24 Hour Extended Release. These medicines include:

- Some heart or blood pressure medicines
- monoamine oxidase inhibitors, medicines used to treat depression
- antacids
- kaolin

These medicines may be affected by Clarityn-D® 24 Hour Extended Release, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Signs and symptoms of overdose

Signs and symptoms of overdose may vary from CNS depression (sedation, apnea, diminished mental alertness, cyanosis, coma, cardiovascular collapse) to stimulation (insomnia, hallucination, tremors or convulsions) which may be fatal. Other signs and symptoms may be euphoria, excitement, rapid heart rate, palpitations, thirst, perspiration, nausea, dizziness, tinnitus (ringing in the ears), ataxia (lack of muscle coordination), blurred vision and hypertension (high blood pressure) or hypotension (low blood pressure). Stimulation is particularly likely in children, as are atropine-like signs and symptoms (dry mouth; fixed, dilated pupils; flushing; hyperthermia (elevated body temperature); and gastrointestinal symptoms).

What should you do in case of an overdose?

In the event of overdose, seek medical help immediately.

How do I store Clarityn-D® 24 Hour Extended Release

Keep the tablets out of reach of children.

Store the tablets at or below 25°C. Protect blister packs from excessive moisture.

For the shelf-life, please refer to labels.

For further information, ask a doctor or pharmacist.