

# Clarityn-D® 12Hour Repetabs

Brand of loratadine and pseudoephedrine sulfate  
Long-Acting, Non-Sedating Antihistamine/Decongestant Tablets



## Product Description

Each Clarityn-D® 12Hr Repetabs tablet contains 5 mg loratadine in the tablet coating and 120 mg pseudoephedrine sulfate equally distributed between the tablet coating and the barrier-coated core. The two active components in the coating are quickly liberated; release of the decongestant in the core is delayed for several hours.

Also contains: acacia, calcium sulfate, carnauba wax, gum rosin, microcrystalline cellulose, oleic acid, medicinal soap, sucrose, talc, titanium dioxide, white wax, zein, lactose anhydrous, corn starch, povidone, magnesium stearate and purified water.

Clarityn-D® 12Hour Repetabs is available in blister packs.

## What is Clarityn-D® 12Hr Repetabs and what is it used for?

Clarityn-D® 12Hour Repetabs relieves symptoms associated with allergic rhinitis and the common cold, including

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

Clarityn-D® 12Hour Repetabs 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 produce narrowing of blood vessels. This leads to clearing of the stuffy or blocked nose.

## How to take Clarityn-D® 12Hour Repetabs?

The recommended dose for Clarityn-D® 12Hour Repetabs in adults and children over 12 years is one tablet twice daily. It does not matter if you take Clarityn-D® 12Hour Repetabs 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 would advise you to take one tablet once daily with a glass of water, with or without food.

Be sure to take Clarityn-D® 12Hour Repetabs 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® 12Hour Repetabs not be taken?

Do not take Clarityn-D® 12Hour Repetabs 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)

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

## Pregnancy and breast-feeding

Safe use of Clarityn-D® 12Hour Repetabs during pregnancy has not been established. Therefore, the product should be used only if the potential benefit justifies the potential risk to the fetus. Please speak to your doctor or pharmacist if you are breastfeeding and intend to take Clarityn-D® 12Hour Repetabs.

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® 12Hour Repetabs.

## What are the precautionary measures to be observed when taking Clarityn-D® 12Hour Repetabs?

Clarityn-D® 12Hour Repetabs should be used with caution in patients with

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

## Laboratory tests

If you are scheduled to have any skin tests for allergies, you should not take Clarityn-D® 12Hour Repetabs for two days before.

## Possible side effects

Like all medicines, Clarityn-D® 12Hour Repetabs can cause side effects, although not everybody gets them.

Some of the side effects include:

- trouble sleeping
- dry mouth
- headache
- sleepiness

Other rare side effects reported included nervousness, dizziness, fatigue, nausea, abdominal distress, appetite changes, thirst, rapid heart rate, sore throat, runny nose, acne, itch, rash, allergic rash, joint pain, confusion, voice disorders, muscle spasm, reduced sensitivity to touch, decreased libido, prickling sensation on the skin, tremor, sensation of whirling, flushing, blood pressure changes, increased sweating, eye disorders, earache, ringing in the ear, taste abnormality, agitation, lack of interest, depression, intense happiness, feeling paranoid, change in bowel habits, indigestion, belching, hemorrhoids, tongue disorder, vomiting, transient abnormal liver function, dehydration, increased weight, palpitation, migraine, bronchospasm, coughing, shortness of breath, nosebleed, nasal congestion, sneezing, nasal irritation, urination disorders, urinary retention, lack of strength, back pain, leg cramps, malaise and rigors.

During the marketing of loratadine, cases of hair loss, severe allergic reaction (including swelling), liver problems, dizziness and convulsion have been reported rarely. 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® 12Hour Repetabs?**

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® 12Hour Repetabs. 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® 12Hour Repetabs, 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) to death 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® 12Hour Repetabs?**

Keep the tablets out of reach of children.

Store the tablets at or below 30°C. Protect blister packs from excessive moisture.

For the shelf-life, please refer to labels.

For further information, ask a doctor or pharmacist.