

# Clarinase Repetabs® Tablets



Each tablet contains:

Loratadine 5 mg

Pseudoephedrine sulphate 120 mg

Inactive and allergenic ingredients: see section 6 "Further information" and the end of section 2 "Important information about some of the ingredients in the medicine".

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

## 1) WHAT IS THE MEDICINE INTENDED FOR?

Clarinase Repetabs is intended to relieve symptoms associated with seasonal allergic rhinitis when both the antihistaminic properties and the nasal decongestant activity are desired.

### Therapeutic group:

Clarinase Repetabs contains a combination of two active ingredients (loratadine and pseudoephedrine sulphate). Loratadine is an antihistamine. Pseudoephedrine sulphate is a decongestant. Antihistamines help reduce allergy symptoms by preventing the effects of a substance called histamine, which is produced by the body when you are allergic to something. Decongestants help reduce nasal congestion.

## 2) BEFORE USING THE MEDICINE

### Do not use the medicine if:

- You are sensitive (allergic) to loratadine, pseudoephedrine sulphate or to any of the other ingredients contained in the medicine. For the list of inactive ingredients, see section 6 "Further information".

### Due to the presence of pseudoephedrine sulphate, do not take Clarinase Repetabs in the following situations:

- if you are taking a medicine to lower blood pressure or for heart disease.
- if you are suffering from glaucoma, difficulty urinating, urinary tract blockage, high blood pressure, heart or blood vessel disease, if you had a hemorrhagic stroke, or if you have an overactive thyroid.
- if you are taking medicines from the monoamine oxidase (MAO) inhibitor class or have stopped taking this medicine within the last 14 days.

### Special warnings regarding use of this medicine:

Certain conditions may make you unusually sensitive to the decongestant pseudoephedrine contained in this medicine.

Before taking Clarinase Repetabs, tell the doctor if:

- you are 60 years of age or older; older adults may be more sensitive to the effects of this medicine.
- you are suffering from diabetes mellitus, stenosing peptic ulcer (an ulcer that led to narrowing of the stomach, small intestine or esophagus), pyloroduodenal blockage (intestinal blockage), bladder neck blockage, if you experienced bronchospasm incidents in the past (difficulty breathing due to tightening of the lung muscles), or problems with the liver, kidneys or bladder.
- you are scheduled to undergo surgery, because you may have to stop taking Clarinase Repetabs for a few days.
- Stop taking the medicine two days before a skin sensitivity test for allergy, since the test results may be affected by this medicine.
- Athletes taking Clarinase Repetabs may have positive doping-tests.

Tell your doctor if you experience the following effects or are diagnosed as suffering from:

- High blood pressure
- Rapid or strong heartbeat
- Irregular heartbeat
- Nausea and headaches or worsening of headaches during treatment with Clarinase Repetabs. Your doctor may recommend stopping the treatment.

One of the ingredients in Clarinase Repetabs, pseudoephedrine sulphate, has the potential to be abused, and large doses of pseudoephedrine sulphate may be toxic.

Isolated cases of acute generalized exanthematous pustulosis (AGEP), a severe skin reaction have been reported, when using preparations containing pseudoephedrine. If you notice signs and symptoms such as fever, erythema or pustular rash (generalized) with small pustules, stop taking the medicine and refer to a doctor.

### Children and adolescents

This medicine is not intended for children under 12 years of age.

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** It is particularly important to tell the doctor or pharmacist if you are taking:

- digitalis, a medicine used to treat certain heart disorders, because the dosage may need to be adjusted.
- alpha-methyl dopa, mecamlamine, reserpine, veratrum alkaloids and guanethidine (to treat blood pressure), because the dosage may need to be adjusted.
- decongestants (oral or nasal), appetite suppressants (diet pills) or amphetamines, because in combination with Clarinase Repetabs, these medicines may raise your blood pressure.
- ergot alkaloids (such as dihydroergotamine, ergotamine, or methylergometrine) to treat migraines; if taken together with Clarinase Repetabs, these medicines may raise your blood pressure.
- linezolid (an antibiotic), bromocriptine (to treat infertility or Parkinson's disease), cabergoline, lisuride and pergolide (to treat Parkinson's disease); if taken together with Clarinase Repetabs, these medicines may raise your blood pressure.
- antacids, because they may increase the effectiveness of Clarinase Repetabs.
- kaolin, because it may lower the effectiveness of Clarinase Repetabs.

### Use of the medicine and food

Clarinase Repetabs can be taken with or without food.

### Use of the medicine and alcohol consumption

Clarinase Repetabs has not been found to increase the effect of alcoholic beverages.

### Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning a pregnancy, consult the doctor or pharmacist before using this medicine.

#### Pregnancy

There is limited information regarding use of Clarinase Repetabs in pregnant women. Use of Clarinase Repetabs is not recommended during pregnancy due to the vasoconstrictive nature of pseudoephedrine.

#### Breastfeeding

Do not use Clarinase Repetabs if you are breastfeeding. Loratadine and pseudoephedrine are secreted in breast milk. Reduced breast milk production in nursing mothers has been reported in association with pseudoephedrine, one of the components in Clarinase Repetabs.

### Driving and using machines

Clarinase Repetabs is not expected to cause sleepiness or reduced alertness when taken at the recommended dosage.

However, very rarely, some people may feel sleepy, which may affect their ability to drive or use machines.

### Important information about some of the ingredients in the medicine

Clarinase Repetabs contains lactose and sucrose. Therefore, if you have been told by the doctor that you are suffering from intolerance to certain sugars, contact your doctor before taking this medicine.

Each tablet contains 156.8 mg lactose monohydrate, 173.23 mg sucrose.

## 3) HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation in accordance with the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

### Adults and adolescents 12 years of age and above:

The recommended dosage is usually one Clarinase Repetabs tablet, twice a day, with a glass of water; with or without food.

### Do not exceed the recommended dosage.

### Duration of treatment:

Do not take this medicine for more than 10 consecutive days, unless instructed to do so by the doctor.

### Method of administration:

This medicine is intended for oral use. Swallow the tablet whole.

Do not crush, break or chew the tablet before swallowing it.

**If you took an overdose, or if a child has accidentally swallowed the medicine,** refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Sleepiness, rapid heartbeat and headaches have been reported in association with an overdose of loratadine, a component of Clarinase Repetabs. Convulsions, rapid heartbeat, nausea and nervousness have been reported in association with an overdose of pseudoephedrine, a component of Clarinase Repetabs.

**If you forgot to take the medicine,** take a dose as soon as possible, and then return to the original dosing schedule.

Do not take a double dose to compensate for a missed dose.

Adhere to the treatment regimen recommended by the doctor.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

If you have further questions regarding the use of the medicine, consult the doctor or pharmacist.

## 4) SIDE EFFECTS

As with any medicine, use of Clarinase Repetabs may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Contact a doctor or pharmacist immediately if you are suffering from a reaction to Clarinase Repetabs that is prolonged, bothersome or you think is serious.

Very common side effects – effects that occur in more than one in ten users:

- trouble sleeping

Common side effects – effects that occur in up to one in 10 users:

- thirst
- nervousness
- drowsiness
- depression
- agitation
- lack of appetite (anorexia)
- dizziness
- dry mouth
- fast heartbeat
- sore throat
- inflammation of the nasal lining
- constipation
- nausea
- headaches
- tiredness

Uncommon side effects – effects that occur in 1-10 in 1000 users:

- confusion
- tremor
- increased sweating
- hot flushes
- altered sense of taste
- abnormal tearing
- ringing in the ears
- irregular heartbeat
- nosebleed
- frequent or abnormal urination
- itching

Isolated cases of acute generalized exanthematous pustulosis (AGEP), a form of severe skin reaction, have been reported when using preparations containing pseudoephedrine.

Very rare side effects – effects that occur in up to one in 10,000 users and have also been reported during the marketing of Clarinase Repetabs:

- severe allergic reaction including: rash, hives and swelling of the face
- vertigo
- convulsions
- heart rhythm disturbances
- high blood pressure
- cough
- narrowing of the airways
- liver problems
- difficulty urinating
- hair loss

Other side effects that were reported for loratadine only, in clinical trials and during the post-marketing period, include increased appetite, rash, and stomach discomfort.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

## 5) HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C. Store in the original package to protect from moisture. Do not freeze.
- Do not use the medicine if you notice any change in the appearance of the tablets.
- Do not discard medicines into the wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer needed. These measures will help protect the environment.

## 6) FURTHER INFORMATION

- In addition to the active ingredients, the medicine also contains:  
Core: Lactose monohydrate, Corn starch, Povidone, Magnesium stearate. Coating: Sucrose, Calcium sulphate anhydrous, Calcium sulphate dihydrate, Talc, Gum rosin nelio, Acacia, Zein, Titanium dioxide, Oleic acid, Cellulose microcrystalline, Soap powder, Carnauba wax, White wax.
- What the medicine looks like and the contents of the package:  
Clarinase Repetabs are white, round, biconvex tablets with a shiny coating, without any foreign particles.  
The tablets come in blisters, in packs of 2, 4, 10, 14, 20, 28, 30, 50 tablets.  
Not all pack sizes may be marketed.
- Registration Holder and address: Bayer Israel Ltd.,  
36 Hacharash St., Hod Hasharon 45240.
- Manufacturer and address: Schering-Plough Labo NV, Heist-op-den-Berg, Belgium.
- This leaflet was checked and approved by the Ministry of Health in 01/2018.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 101 67 28568 00.