Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Clarinase Repetabs
Prolonged-release tablets

Each tablet contains:
Loratadine 5 mg
Pseudoephedrine sulphate 120 mg

Inactive ingredients and allergens: see section 2 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

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

1) What is this medicine intended for?

Clarinase Repetabs is intended for the relief of symptoms of 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 substances (loratadine and pseudoephedrine sulphate). Loratadine is an antihistamine. Pseudoephedrine sulphate is a decongestant. Antihistamines help reduce allergy symptoms by stopping 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 this medicine

Do not use this medicine:

- If you are sensitive (allergic) to loratadine, pseudoephedrine or to any of the other ingredients in this medicine. For a list of the inactive ingredients, see section 6 "Additional information".

Due to the presence of pseudoephedrine, do not take Clarinase Repetabs:

- If you are taking medicine to lower blood pressure or for heart disease.
- If you have glaucoma, difficulty in urinating, urinary tract blockage, high blood pressure, heart or blood vessel disease, a history of haemorrhagic stroke, you have other risk factors that increase the chance of having a stroke or you have an overactive thyroid.
- If you are taking monoamine oxidase (MAO) inhibitors or have stopped taking this medication therapy within the last 14 days, are taking other vasoconstrictors (such as bromocripitine, pergolide, lisuride, cabergoline, ergotamine, dihydroergotamine) or other medicines used to relieve nasal congestion, either by nasal route or by oral route (such as those that contain phenylpropanolamine, phenylephrine, ephedrine, oxymetazoline or naphazoline).
- If you are pregnant or breastfeeding.
- If you have very high blood pressure (severe hypertension) or hypertension not controlled by your medication, heart or blood vessel disease or a history of stroke.
- If you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure.

Special warnings about using this medicine:
There are certain conditions that may make you unusually sensitive to the decongestant pseudoephedrine contained in this medicine.

Before using Clarinase Repetabs, tell your doctor if:
- You are 60 years of age or older, because older adults may be more sensitive to the effects of this medicine.
- You have diabetes mellitus, stenosing peptic ulcer (ulcer leading to the narrowing of the stomach, small intestine or oesophagus), pyloroduodenal blockage (intestine blockage), bladder neck blockage, previous history of bronchospasm (difficulty breathing due to tightening of the lung muscles), or problems with your liver, kidneys or bladder.
- You are scheduled to have surgery, because you may have to stop taking Clarinase Repetabs for a few days.

Tell your doctor if you experience or are diagnosed with any of the following effects:
- High blood pressure
- Fast or pounding heartbeat
- Irregular heartbeat
- Feeling sick and headaches or worsening headaches during treatment with Clarinase Repetabs. Your doctor may advise you to stop your treatment.

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

Isolated cases of acute generalised exanthematous pustulosis (AGEP), **which is a severe skin reaction** have been reported, when using medicines containing pseudoephedrine. If you notice signs and symptoms such as fever, erythema or pustular rash (generalised) with pustules, stop taking the medicine and consult a doctor immediately.

Sudden abdominal pain or rectal bleeding may occur during use of Clarinase Repetabs due to inflammation of the colon (ischaemic colitis). If you develop these gastro-intestinal symptoms, stop taking the medicine and contact a doctor or seek medical attention immediately. See section 4.

Reduction of blood flow to your optic nerve may occur when using Clarinase Repetabs. If you develop sudden loss of vision, stop taking the medicine and contact a doctor or seek medical attention immediately. See section 4.

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using Clarinase Repetabs immediately and seek immediate medical assistance if you develop symptoms of PRES or RCVS (see section 4 “Side effects” for symptoms).

Children and adolescents
This medicine is not indicated for children under 12 years of age.

Tests and follow-up
- Stop taking the medicine two days before a skin allergy test, as the results of the test may be affected by the medicine.
- Athletes taking Clarinase Repetabs may have positive doping-tests.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- Digitalis, a medicine used to treat certain heart disorders, because the dosage may have to be adjusted.
- α-methyldopa, mecamylamine, reserpine, 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 together with Clarinase Repetabs, these medicines may raise your blood pressure.
- Ergot alkaloids (such as dihydroergotamine, ergotamine, or methylergometrine) to treat migraines. Together with Clarinase Repetabs, these medicines may raise your blood pressure.
- Linezolide (a type of antibiotic), bromocriptine (for infertility or Parkinson's disease), cabergoline, lisuride and pergolide (to treat Parkinson's disease). Together with Clarinase Repetabs, these medicines may raise your blood pressure.

Using this medicine and food
You can take Clarinase Repetabs either with or without food.

Using this medicine and alcohol consumption
Clarinase Repetabs has not been shown to add to the effects of alcoholic drinks.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy
Do not take Clarinase Repetabs if you are pregnant.

Breastfeeding
Loratadine and pseudoephedrine are excreted in breast milk. Decreased milk production in nursing mothers has been reported with pseudoephedrine, one of the ingredients of Clarinase Repetabs. Given that it is not possible to rule out risk to a newborn or baby, do not use Clarinase Repetabs if you are breastfeeding.

Driving and using machines
Clarinase Repetabs is not expected to cause drowsiness or make you less alert after taking the recommended dosage.
However, very rarely, some people experience drowsiness, which may affect their ability to drive or operate machines.

Important information about some of this medicine's ingredients
Clarinase Repetabs contains lactose and sucrose; thus if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3) How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dose or about how to take this medicine.

Only a doctor will determine the dose and how this medicine should be taken.

In adults and adolescents 12 years of age and over, the recommended dosage is usually:
One Clarinase Repetabs tablet twice daily with a glass of water, with or without food.

Do not exceed the recommended dose.

Duration of treatment:

Do not take this medicine for more than 10 days continuously unless a doctor has instructed you to do so. If your symptoms do not improve or worsen after 10 days, consult a doctor.

Method of administration:
This medicine is for oral use. Swallow the tablet whole.
Do not crush, break or chew the tablet before swallowing so you do not damage the special coating.

If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Sleepiness, rapid heartbeat and headaches have been reported with overdoses of loratadine, an ingredient in Clarinase Repetabs. Convulsions, rapid heartbeat, nausea and nervousness have been reported with overdoses of pseudoephedrine, an ingredient in Clarinase Repetabs.

If you forget 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 make up for a forgotten dose.

Adhere to the treatment as recommended by the doctor.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4) <u>Side effects</u>

Like all medicines, use of Clarinase Repetabs may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.
Contact a doctor or pharmacist immediately if you have any reaction to Clarinase Repetabs that is prolonged, bothersome or that you think is serious.
In case of sudden onset of fever, reddening of the skin, or many small pustules, these are possible symptoms of Acute Generalised Exanthematous Pustulosis (AGEP), **a type of severe skin reaction** of unknown frequency. These symptoms may occur within the first 2 days of treatment with Clarinase Repetabs. See section 2. Stop using Clarinase Repetabs if you develop these symptoms and contact your doctor or seek medical attention immediately.
Stop using Clarinase Repetabs immediately and seek urgent medical attention if you develop symptoms that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). The symptoms include:

- severe headache with a sudden onset (side effects of unknown frequency)
- feeling sick (common side effect)
- vomiting (side effect of unknown frequency)
- confusion (uncommon side effect)
- seizures (very rare side effect)
- changes in vision (side effect of unknown frequency)

Very common side effects - affect more than 1 in 10 users:

- Trouble sleeping

Common side effects - affect up to 1 in 10 users:

- Thirst
- Nervousness
- Drowsiness
- Depression
- Agitation
- Loss of appetite (anorexia)
- Dizziness

- Dry mouth
- Fast heartbeat
- Sore throat
- Inflammation of the nasal lining
- Constipation
- Headaches
- Tiredness

Uncommon side effects - affect 1-10 in 1000 users:
- Tremor
- Increased sweating
- Hot flushes
- Altered taste
- Abnormal tearing
- Ringing in the ears
- Irregular heartbeat
- Nosebleed
- Frequent or abnormal urination
- Itching

Very rare side effects - affect up to 1 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 disorders
- High blood pressure
- Cough
- Narrowing of the airways
- Liver problems
- Difficulty urinating
- Hair loss

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

Side effects of unknown frequency:
- Weight gain.
- Inflammation of the colon due to insufficient blood supply (ischaemic colitis).
- Reduced blood flow to the optic nerve (ischaemic optic neuropathy).
- Serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult a doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:
https://sideeffects.health.gov.il

5) How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

- **Storage conditions:** Store below 25˚C. Store in the original package in order to protect from moisture. Do not freeze.

- Do not use this medicine if you notice any change in the appearance of the tablets.

- Do not throw away medicines via wastewater or household waste. Ask a pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6) Additional information

- In addition to the active ingredients, this 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 contents of the pack:

White, round, biconvex tablets with a shiny coating, without any foreign particles.
The tablets come in blisters, in packs of 2, 4, 6, 10, 14, 20, 28, 30, 50 tablets.
Not all pack sizes may be marketed.

- **Registration holder and importer's name and address:** Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 45240.

- This leaflet was revised in March 2024.

- Registration number of the medicine in the Ministry of Health's National Drug Registry:
  101 67 28568 00.