Package leaflet: Information for the user

***Clarinase Repetabs* 5 mg/120 mg prolonged-release tablets**
loratadine/pseudoephedrine sulphate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist <or nurse> have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor . This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 10 days.

What is in this leaflet

1. What *Clarinase Repetabs* is and what it is used for
2. What you need to know before you take *Clarinase Repetabs*
3. How to take *Clarinase Repetabs*
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1 What *Clarinase Repetabs* is and what it is used for

What *Clarinase Repetabs* is
Clarinase Repetabs contains a combination of two medicines (loratadine and pseudoephedrine sulphate). Loratadine is an antihistamine and pseudoephedrine sulphate is a decongestant.

How *Clarinase Repetabs* works
Clarinase Repetabs help to reduce your allergy or common cold symptoms by stopping the effects of a substance called "histamine", which is produced by the body when you are allergic to something. Decongestants help to clear nasal congestion.

When *Clarinase Repetabs* should be used
Clarinase Repetabs relieve symptoms associated with seasonal allergic rhinitis (hay fever), such as, sneezing, runny or itchy nose, and eyes, when accompanied by nasal congestion in adults and children 12 years of age and over.

2. What you need to know before you take *Clarinase Repetabs*

Do not take *Clarinase Repetabs* if
- you are allergic (hypersensitive) to loratadine, pseudoephedrine or to any of the other ingredients of this medicine (listed in section 6).

Due to the presence of pseudoephedrine, do not take *Clarinase Repetabs* if
- you are also receiving heart or blood pressure medicine.
- you have glaucoma, difficulty in urinating, urinary tract blockage, high blood pressure (hypertension) or hypertension not controlled by your medication, heart or blood vessel disease, a history of stroke, or an overactive thyroid.
- you are receiving monoamine oxidase (MAO) inhibitor therapy or have stopped taking this medicine within the last 14 days.
- you have severe acute (sudden) or chronic (long-term) kidney disease or kidney failure.

Warnings and precautions
Certain conditions may make you unusually sensitive to the decongestant pseudoephedrine contained in this medicine.
Talk to your doctor or pharmacist before taking *Clarinase Repetabs* if
- you are 60 years of age or older, Older adults may be more sensitive to the effects of this medicine
- you have diabetes mellitus (sugar diabetes), stenosing peptic ulcer (ulcer leading to the narrowing of the stomach, small intestine or esophagus), pyloroduodenal blockage (intestine blockage), blockage of the vesical cervix (bladder neck blockage), previous history of bronchospasm (difficulty breathing due to tightening of the lung muscles), or problems with your liver, kidney, or bladder.
- you are scheduled to have surgery, because you may have to stop taking *Clarinase Repetabs* for a few days.
- you are taking digitalis, a medicine used to treat certain heart disorders, because the dosage may have to be adjusted.
- you are taking alpha-methyldopa, mecamylamine, reserpine and guanethidine for blood pressure, because the dose may need to be adjusted.
- you are taking decongestants (oral or nasal), appetite suppressants (diet pills), or amphetamines, because together with *Clarinase Repetabs*, these medications may raise your blood pressure.
- you are taking ergot alkaloids (such as dihydroergotamine, ergotamine, or methylergometrine) for migraines. Together with *Clarinase Repetabs*, these medications may raise your blood pressure.
- you are taking linezolide (an antibiotic), bromocriptine (for infertility or Parkinson's disease), cabergoline, lisuride and pergolide (for Parkinson's disease). Together with *Clarinase Repetabs*, this medication may raise your blood pressure.

- you are scheduled to have skin tests for allergies you should not take *Clarinase Repetabs* for two days before having these tests, because this medicine may affect test results.

Tell your doctor if you experience or are diagnosed with any of the following:
- high blood pressure,
- a fast or pounding heartbeat,
- abnormal heart rhythm,
- feeling sick and headache or increase headache while using *Clarinase Repetabs.* Your doctor may advise you to stop your treatment.

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

If you develop a feverish generalised erythema associated with pustules, stop taking *Clarinase Repetabs* and contact your doctor or seek medical attention immediately. See section 4.

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

Reduction of blood flow to your optic nerve may occur with *Clarinase Repetabs*. If you develop sudden loss of vision, stop taking *Clarinase Repetabs* and contact your 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 that may be signs of PRES or RCVS (see section 4 "Possible side effects" for symptoms).

Children
Do not give this medicine to children less than 12 years of age.

Other medicines and *Clarinase Repetabs*
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines obtained without a prescription.

***Clarinase Repetabs* with alcohol**
Clarinase Repetabs has not been shown to add to the effects of an alcoholic drink.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
Do not take *Clarinase Repetabs* if you are pregnant.

Breast-feeding
Do not take *Clarinase Repetabs* if you are breast-feeding.

Loratadine and pseudoephedrine are excreted in breast milk. Decreased milk production in nursing mothers has been reported with pseudoephedrine, a component of *Clarinase Repetabs*.

Driving and using machines
At the recommended dose, *Clarinase Repetabs* is not expected to cause you to be drowsy or less alert. However, very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

***Clarinase Repetabs* contain lactose and sucrose**
Clarinase Repetabs prolonged-release tablets contain 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.

Laboratory tests
Athletes taking *Clarinase Repetabs* may have positive doping-tests.

3. How to take *Clarinase Repetabs*

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take:
Adults and adolescents 12 years of age and over
The recommended dose is one *Clarinase Repetabs* prolonged-release tablet **twice** daily with a glass of water, with or without food.

This medicine is for oral use.
Swallow the tablet whole; do not crush, break or chew the tablet before swallowing.

Do not take more *Clarinase Repetabs* than recommended on the label or take tablets more often than recommended.
Do not take this medicine for more than 10 days continuously unless your doctor tells you to do so.

If you take more *Clarinase Repetabs* than you should
If you take an overdose, tell your doctor or pharmacist straight away. Sleepiness, rapid heartbeat and headache have been reported with overdoses of loratadine, a component of *Clarinase Repetabs*. Convulsions, rapid heartbeat, nausea and nervousness have been reported with overdoses of pseudoephedrine, a component of *Clarinase Repetabs*.

If you forget to take *Clarinase Repetabs*
- If you forget to take your dose, take it as soon as you remember, then continue to take it as usual.

- Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Contact a doctor or pharmacist immediately if you have any reaction to *Clarinase Repetabs* that continues, is bothersome or that you think is serious.

Not known: frequency cannot be estimated from the available data

- serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).

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). These include:

- severe headache with a sudden onset
- feeling sick
- vomiting
- confusion
- seizures changes in vision

Very common side effects (may affect more than 1 in 10 people) associated with *Clarinase Repetabs* 5 mg/120 mg prolonged-release tablets include: trouble sleeping.

Common side effects (may affect up to 1 in 10 people) associated with *Clarinase Repetabs* 5 mg/120 mg prolonged-release tablets include: thirst, nervousness, drowsiness, depression, agitation, anorexia, dizziness, dry mouth, fast heartbeat, sore throat, inflammation of the nasal lining, constipation, nausea, headache and tiredness.

Side effects occurring less frequently include: confusion, tremor, increased sweating, hot flushes, altered taste, abnormal tearing of the eyes, ringing in the ears, irregular heartbeat, nosebleed, frequent or abnormal urination and itching.

The following **very rare** side effects (may affect up to 1 in 10,000 people) have also been seen during the marketing of *Clarinase Repetabs*: severe allergic reaction including rash, hives, and swelling of the face, vertigo, convulsions, abnormal heart rhythms, high blood pressure, cough, narrowing of the airways, liver problems, difficulty urinating, and hair loss have been reported.

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

The frequency of the following side effects is not known:

- weight increased
- Sudden onset of fever, reddening of the skin, or many small pustules (possible symptoms of Acute Generalized Exanthematous Pustulosis - AGEP) 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.
- Inflammation of the colon due to insufficient blood supply (ischaemic colitis)
- Reduced blood flow to the optic nerve (Ischaemic optic neuropathy)

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects notlisted in this leaflet. You can also report side effects directly via the ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store *Clarinase Repetabs*

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original package in order to protect from moisture. Do not freeze.
- Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.
- Do not use this medicine if you notice any change in the appearance of the tablets.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What *Clarinase Repetabs* contains

- The active substances in *Clarinase Repetabs* prolonged-release tablets are loratadine 5 mg and pseudoephedrine sulphate 120 mg.
- The other ingredients are: core – lactose monohydrate; maize starch; povidone; and magnesium stearate; coating – acacia; calcium sulphate anhydrous; calcium sulphate dihydrate; carnauba wax; microcrystalline cellulose; oleic acid; colophonium; soap powder; sucrose; talc; titanium dioxide; white beeswax; and zein. See section 2 'Clarinase Repetabs contain lactose and sucrose'

What *Clarinase Repetabs* looks like and contents of the pack

Clarinase Repetabs 5 mg/120 mg prolonged-release tablets are available in blister strips in pack sizes of 1, 7, 10, 14, 20, 28, 30, 50 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Bayer SA-NV,
Kouterveldstraat 7A 301,
B-1831 Diegem (Machelen),
Belgium

Manufacturer:
SAG Manufacturing, S.L.U.
Carretera N-1, Km 36
28750, San Agustin de Guadalix
Madrid

Spain

This medicine is authorised in the Member States of the European Economic Area under the following names:

Clarinase: Austria
Clarinase Repetabs: Belgium
Clarityne-D 120/5: Greece
Narine Repetabs 5mg/120mg: Spain
Claridon: Portugal

This leaflet was last revised in 07/2024