

**Package leaflet: Information for the patient/user**

**MACIMORELIN 60 mg granules for oral suspension in sachet**  
macimorelin

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you take this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What MACIMORELIN is and what it is used for
2. What you need to know before MACIMORELIN is given
3. How MACIMORELIN is given
4. Possible side effects
5. How MACIMORELIN is stored
6. Contents of the pack and other information

**1. What MACIMORELIN is and what it is used for**

The medicine contains an active substance called macimorelin. Macimorelin acts like a natural hormone and causes the pituitary gland to release growth hormone into the blood stream.

MACIMORELIN is used in adults to test the body's ability to produce growth hormone. It is used when your doctor thinks that you may not have enough growth hormone (adult growth hormone deficiency). This is not a treatment for patients who do not have enough growth hormone. It is a test that helps your doctor to diagnose this condition.

**2. What you need to know before MACIMORELIN is given**

**You must not be given MACIMORELIN**

- if you are allergic to macimorelin or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your doctor or nurse before you are given MACIMORELIN.

**Warnings and precautions**

To ensure that the test results are reliable, you need to follow the rules below:

- Fasting - you must not eat for at least 8 hours before the test, and during the test.
- Physical exercise - avoid strenuous physical activity 24 hours before the test.
- Drinking - up to 100 mL of still water is allowed each within 1 hour before as well as within 1 hour after macimorelin intake.

Talk to your doctor or nurse if:

- you have recently been treated with growth hormone (somatotropin) or with medicines that affect the secretion of growth hormone by the pituitary gland. You need to stop such treatment at least 1 month before the test.
- you have recently been treated for Cushing's disease (disorder which results in high levels of the hormone cortisol) or if you are receiving a high dose of hydrocortisone medicine, the test may lead to false positive test results.
- your body is lacking any other hormone e.g. cortisol, thyroid or sex hormones, vasopressin (in diabetes insipidus), this should be adequately replaced before testing for growth hormone deficiency. Other hormone deficiencies if untreated could lead to inaccurate results in the growth hormone stimulation test.
- you have heart disease or problems with your heart rhythm (including congenital or acquired long QT syndrome or a history of so called torsades de pointes tachycardias). MACIMORELIN can cause changes in the ECG (electrocardiogram) including QT prolongation that are associated with an increased risk for arrhythmias. If occurring, such changes would be timely limited and not last long.

If any of the above applies to you, or if you are not sure, talk to your doctor or nurse before you are given this medicine.

MACIMORELIN is indicated as a single-dose diagnostic test. No information is available on the safety and effects of macimorelin during long-term use.

Potentially re-test needed in early disease

If the adult growth hormone deficiency just recently started and if it is due to an injury in a section of the brain called hypothalamus, then the test result could be negative although you have the disease. In such a situation, a repetition of the test may be required.

**Children and adolescents**

MACIMORELIN must not be used in children and adolescents aged below 18 years, because the safety and effectiveness in these groups have not yet been established.

**Other medicines and MACIMORELIN**

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking medicines that can alter your heart rhythm, such as:

- medicines to treat psychosis (such as chlorpromazine, haloperidol)
- medicines to treat infections (antibiotics such as erythromycin, clarithromycin, moxifloxacin)
- medicines to correct the heart rhythm (antiarrhythmic medicines such as amiodarone, procainamide, quinidine or sotalol)
- any other medicines that can prolong the QT interval or inducing torsades de pointes

Tell your doctor if you are taking medicines that could increase the breakdown of macimorelin such as specific medicines to treat:

- seizures/epilepsy (carbamazepine, eslicarbazepine, fosphenytoin, oxcarbazepine, phenobarbital, phenytoin, primidone)

- sleep disorder (modafinil, pitolisant)
- mild to moderate depressive episodes (St. John's wort (*Hypericum perforatum*))
- cystic fibrosis (lumacaftor)
- infections (antibiotics such as rifabutin, rifampicin)
- HIV (efavirenz, nevirapine)
- type 2 diabetes (pioglitazone)
- cancer (dabrafenib, enzalutamide)

Tell your doctor if you are taking medicines that may impact the accuracy of the diagnostic test. Avoid concomitant use with medicines:

- that could have a direct influence on growth hormone secretion by the pituitary gland: such as somatostatin, insulin, glucocorticoids, acetylsalicylic acid, indometacin
- that could increase growth hormone levels: such as clonidine, levodopa, insulin
- that could reduce the growth hormone response to macimorelin such as: atropine, propylthiouracil, growth hormone medicines

#### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before this medicine is given to you. MACIMORELIN is not recommended during pregnancy. If you are a woman able to have children, you must use effective contraceptive methods to ensure you are not pregnant at the time of the test. If you are breast-feeding or intend to breast-feed, a risk to the suckling child cannot be excluded. Please ask your doctor whether to discontinue breast-feeding or to abstain from the macimorelin test.

#### **Driving and using machines**

Dizziness can occur with MACIMORELIN. If this happens, do not drive or use machines.

#### **MACIMORELIN contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

#### **MACIMORELIN contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say it is essentially "sodium-free".

### **3. How MACIMORELIN is given**

A healthcare professional must supervise the preparation and use of MACIMORELIN. Instructions are given at the end of this leaflet on how to prepare the test.

The description in this leaflet is for your information on the testing procedure.

You must be fasting for at least 8 hours before you are given MACIMORELIN. You may not perform strenuous physical exercises 24 hours before the test. You can drink up to 100 mL of still water within 1 hour before and within 1 hour after intake of MACIMORELIN.

#### **Dose**

The recommended dose is 0.5 mg MACIMORELIN per kg body weight.

This corresponds to a volume of 1 mL of the prepared suspension per kg body weight.

You have to drink the complete test dose within 30 seconds.

You will have three blood samples taken to measure growth hormone, one sample each at 45, 60 and 90 minutes after taking the test dose.

#### **If you are given more MACIMORELIN than you should**

If you are given more MACIMORELIN than you should, tell your doctor or nurse. Possible side effects in cases of overdosing could include headache, nausea, vomiting and diarrhoea. In case you should have heart rhythm disturbances, an ECG monitoring will be performed.

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

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

#### **Common side effects** (may affect up to 1 in 10 people):

- a bitter or metallic taste (dysgeusia)
- tiredness
- headache
- feeling sick (nausea)
- dizziness
- diarrhoea
- feeling hot

These side effects are mostly mild, do not last long, and usually go away quickly without treatment.

#### **Uncommon side effects** (may affect up to 1 in 100 people):

- abdominal pain
- feeling cold
- hunger
- palpitations
- lower than normal heart rate (sinus bradycardia)
- sleepiness
- thirst
- tremor
- vertigo

#### **Frequency not known** (cannot be estimated from the available data):

- changes in the electrocardiogram (ECG)

### Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How MACIMORELIN is stored

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton and the sachet after EXP. The expiry date refers to the last day of that month.

Store in the original package, in order to protect from light and moisture.

Store in a refrigerator (2°C – 8°C).

### Unopened sachet

The shelf life of a sachet is 5 years.

### Reconstituted suspension

The suspension must be taken within 30 minutes after preparation.

Any remaining suspension must be discarded by your doctor or nurse according to local regulations.

Do not throw away any medicines via wastewater or household waste. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What MACIMORELIN contains

- The active substance is macimorelin. Each sachet contains 60 mg macimorelin (as acetate). 1 mL of the reconstituted suspension contains 500 micrograms macimorelin.
- The other ingredients are: lactose monohydrate (see section 2 under ‘MACIMORELIN contains lactose’), colloidal anhydrous silica, crospovidone type A, saccharin sodium dihydrate and sodium stearyl fumarate (see section 2 under ‘MACIMORELIN contains sodium’).

### What MACIMORELIN looks like and contents of the pack

MACIMORELIN is presented as white to off-white granules for oral suspension. Each sachet contains 1,817 mg granules. Each cardboard box contains 1 sachet.

### Marketing Authorisation Holder

Atnahs Pharma UK Limited.

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Miles Gray Road

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### Manufacturer

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Germany

**This leaflet was last revised in November 2023.**

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The following information is intended for healthcare professionals only:

### DIRECTIONS FOR PREPARATION AND USE

#### The suspension must be prepared and administered by a healthcare professional.

Items needed: MACIMORELIN sachet, tap water in decanter, graduated glass or transparent plastic container, stirring device, 50 mL graduated syringe without needle, drinking glass

#### Step 1

Weigh the patient.

#### Step 2

Determine the number of MACIMORELIN sachets needed based on body weight: one sachet will be required for a patient weighing up to 120 kg, two sachets will be required if the patient weighs more than 120 kg.

#### Step 3

Add required volume of water in a graduated glass or transparent plastic container. Dissolve the entire contents of the sachet in water: one sachet in 120 mL, two sachets in 240 mL, as applicable.

Stir the suspension gently for 2 minutes (a small amount of undissolved particles will remain giving a slightly turbid suspension). The suspension should be stirred until it is slightly turbid without particles at the bottom of the container. The suspension should be stirred again, when some particles settle at the bottom of the container for example after the suspension is left standing for some time.

#### Step 4

Determine the volume of suspension needed for the recommended macimorelin dose of 0.5 mg/kg. The suspension volume in mL equals the patient's body weight in kg. For example, a 70 kg patient will require 70 mL of the macimorelin suspension.

Measure the required volume using a 50 mL graduated syringe without a needle.

Transfer the measured amount to a drinking glass.

Step 5

Have the patient drink the entire content of the drinking glass within 30 seconds.

The suspension must be used within 30 minutes after preparation. Any suspension that remains must not be stored and must be discarded.

Any unused medicine or waste material should be disposed in accordance with local requirements.

Step 6

Draw venous blood samples for growth hormone determination at 45, 60 and 90 minutes after administration.

Step 7

Prepare plasma or serum samples and send to a laboratory for growth hormone determination.