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Macimorelin Aeterna Zentaris (*macimorelin*)

An overview of Macimorelin Aeterna Zentaris and why it is authorised in the EU

What is Macimorelin Aeterna Zentaris and what is it used for?

Macimorelin Aeterna Zentaris is a medicine used to test the ability of the body to produce growth hormone. It is used by doctors to diagnose growth hormone deficiency, a condition where the patient does not have enough growth hormone. It is not used to treat patients with the condition.

Macimorelin Aeterna Zentaris contains the active substance macimorelin.

How is Macimorelin Aeterna Zentaris used?

Macimorelin Aeterna Zentaris is available as granules that are dissolved in water and taken by mouth. The recommended dose is 0.5 mg per kg body weight which the patient should take once. The doctor then takes blood samples 45, 60 and 90 minutes later to see how much growth hormone the body has produced.

Macimorelin Aeterna Zentaris can only be obtained with a prescription and its use must be supervised by a healthcare professional experienced in diagnosing growth hormone deficiency. For more information about using Macimorelin Aeterna Zentaris, see the package leaflet or contact your doctor or pharmacist.

How does Macimorelin Aeterna Zentaris work?

The active substance in Macimorelin Aeterna Zentaris, macimorelin, stimulates the release of growth hormone into the blood by activating receptors (targets) found on cells in the pituitary gland, a gland located at the base of the brain. The level of growth hormone in the blood is then measured and indicates whether or not the body is able to produce growth hormone.

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What benefits of Macimorelin Aeterna Zentaris have been shown in studies?

Macimorelin Aeterna Zentaris was compared with another test commonly used to diagnose growth hormone deficiency, called insulin tolerance test (ITT), in one main study.

The study involved 166 adults who had either a high, intermediate or low likelihood of having growth hormone deficiency, or who were confirmed not to have growth hormone deficiency. Among them, 140 were tested with both Macimorelin Aeterna Zentaris and ITT.

Overall, 94% of people who tested negative for growth hormone deficiency with ITT also tested negative with Macimorelin Aeterna Zentaris; 74% of people who tested positive with ITT also tested positive with Macimorelin Aeterna Zentaris. This means that, although Macimorelin Aeterna Zentaris might not diagnose all cases of disease, it can help to confirm presence of the disease.

What are the risks associated with Macimorelin Aeterna Zentaris?

The most common side effects with Macimorelin Aeterna Zentaris (which may affect up to 1 in 10 people) are a bitter or metallic taste, tiredness, headache, nausea (feeling sick), dizziness, diarrhoea and feeling hot. Macimorelin Aeterna Zentaris may also cause a change in heart rhythm. Overall, the side effects were mostly mild and short-lasting, with no need for a specific treatment.

For the full list of side effects and restrictions with Macimorelin Aeterna Zentaris, see the package leaflet.

Why is Macimorelin Aeterna Zentaris authorised in the EU?

Macimorelin Aeterna Zentaris gave a similar number of negative test results for growth hormone deficiency as a comparator test; however, it gives fewer positive test results than the comparator. EMA considered that it is a priority to avoid over-diagnosis of adult growth hormone deficiency and that Macimorelin Aeterna Zentaris helps confirm positive diagnosis and so avoid unnecessary treatment of patients with a false positive test result.

In terms of safety, the main concern was that the medicine may change heart rhythm. However this risk is considered small as patients take only one dose of the medicine and are supervised by their doctor. On the whole, Macimorelin Aeterna Zentaris has fewer side effects than the comparator test, which temporarily lowers the level of sugar in the blood.

EMA therefore decided that Macimorelin Aeterna Zentaris's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Macimorelin Aeterna Zentaris?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Macimorelin Aeterna Zentaris have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Macimorelin Aeterna Zentaris are continuously monitored. Side effects reported with Macimorelin Aeterna Zentaris are carefully evaluated and any necessary action taken to protect patients.

Other information about Macimorelin Aeterna Zentaris

Macimorelin Aeterna Zentaris received a marketing authorisation valid throughout the EU on 11 January 2019.

Further information on Macimorelin Aeterna Zentaris can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/macimorelin-aeterna-zentaris.

This overview was last updated in 01-2019.