15 November 2018
EMA/CHMP/777751/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Macimorelin Aeterna Zentaris

macimorelin

On 15 November 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Macimorelin Aeterna Zentaris intended for the diagnosis of growth hormone deficiency in adults. The applicant for this medicinal product is Aeterna Zentaris GmbH.

Macimorelin Aeterna Zentaris will be available as 60 mg granules for oral solution. The active substance of Macimorelin Aeterna Zentaris is macimorelin, a peptide mimetic with growth hormone secretagogue activity similar to ghrelin (ATC code: V04CD06). Macimorelin stimulates growth hormone release by activating growth hormone secretagogue receptors present in the pituitary and hypothalamus.

The benefit with Macimorelin Aeterna Zentaris is its ability to confirm diagnosis of growth hormone deficiency with high sensitivity and specificity in adult patients. The most common side effects are dysgeusia, dizziness, headache, fatigue, feeling hot, nausea and diarrhoea.

The full indication is:

"This medicinal product is for diagnostic use only.

Macimorelin Aeterna Zentaris is indicated for the diagnosis of growth hormone deficiency (GHD) in adults (see section 5.1)."

It is proposed that the use of Macimorelin Aeterna Zentaris be supervised by a physician or healthcare professional experienced in diagnosing growth hormone deficiency

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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