25 April 2025
EMA/CHMP/132414/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Oczyesa

octreotide

On 25 April 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Oczyesa[2], intended for the maintenance treatment of adults with acromegaly.

The applicant for this medicinal product is Camurus AB.

Oczyesa will be available as a 20 mg prolonged-release solution for injection in a pre-filled pen. The active substance of Oczyesa is octreotide, a synthetic derivative of naturally occurring somatostatin, a hypothalamic hormone (ATC code: H01CB02). Octreotide inhibits pathologically increased secretion of growth hormone in patients with acromegaly.

The benefits of Oczyesa are the reduction and, in many cases, normalisation of insulin-like growth factor 1 (IGF-1) and growth hormone levels in patients with acromegaly, as shown in two phase 3 studies. The first one was a 24-week, randomised, double-blind, placebo-controlled, multicentre study and the second one a 52-week, open-label, multicentre study. The most common side effects with Oczyesa include gastrointestinal disorders, nervous system disorders, hepatobiliary disorders, metabolism and nutritional disorders and injection site reactions.

Oczyesa is a hybrid medicine[3] of Sandostatin, which has been authorised in the EU since 18 November 1988. Oczyesa contains the same active substance as Sandostatin but as a different salt and is available at a higher strength and in a different pharmaceutical form. Studies have demonstrated the satisfactory efficacy and safety of Oczyesa in the treatment of patients already well-controlled with other somatostatin analogues. The full indication is:

> Oczyesa is indicated for maintenance treatment in adult patients with acromegaly who have responded to and tolerated treatment with somatostatin analogues.

[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
[2] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained
[3] Hybrid applications rely in part on the results of pre-clinical tests and clinical trials for a reference product and in part on new data

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The recommended dose is 20 mg octreotide every 4 weeks administered by a single subcutaneous injection.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.