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Oczyesa (*octreotide*)

An overview of Oczyesa and why it is authorised in the EU

What is Oczyesa and what is it used for?

Oczyesa is a medicine used for the maintenance (long-term) treatment of acromegaly, a condition where a pituitary adenoma (a non-cancerous tumour in a small gland located at the base of the brain) produces too much growth hormone causing high levels of insulin-like growth factor-1 (IGF-1). This leads to excessive growth of tissues and bones and can also cause diabetes, hypertension (high blood pressure) and cardiovascular disease (conditions affecting the heart and blood circulation).

Oczyesa is used in adults who have previously responded to and tolerated treatment with other somatostatin analogues (man-made (synthetic) versions of the hormone somatostatin).

Oczyesa contains the active substance octreotide and is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but there are certain differences between the two. The reference medicine for Oczyesa is Sandostatin, which is available as a solution for injection at lower strengths than Oczyesa and is also authorised for the treatment of acromegaly.

How is Oczyesa used?

Oczyesa can only be obtained with a prescription.

It is available as a prolonged-release solution for injection in pre-filled pens. Prolonged release means that the active substance is released slowly over a few weeks after being injected. Oczyesa is given once every 4 weeks as an injection under the skin in the belly, thigh or buttock.

Patients switching to treatment with Oczyesa from other somatostatin analogues containing octreotide or lanreotide should take their first dose of Oczyesa at the end of the daily or monthly dosing interval of the previous treatment.

After training, patients may inject Oczyesa themselves if the doctor considers it appropriate.

For more information about using Oczyesa, see the package leaflet or contact your doctor or pharmacist.

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How does Oczyesa work?

The active substance in Oczyesa, octreotide, is a synthetic version of the hormone somatostatin which blocks the release of growth hormone in the pituitary gland. When the medicine attaches to somatostatin receptors (targets), it lowers the levels of growth hormone and as a result also lowers the levels of IGF-1. This is expected to improve disease symptoms, including those related to diabetes and cardiovascular disease.

What benefits of Oczyesa have been shown in studies?

A main study involved 72 adults with acromegaly who were already being treated with another long-acting somatostatin analogue and were responding to treatment. The study compared Oczyesa with placebo (a dummy treatment). The main measure of effectiveness was the proportion of patients who still had normal levels of IGF-1 between 22 and 24 weeks of treatment. Normal levels of IGF-1 are an established measure for good disease control.

The results showed that around 72% (35 out of 48) of patients receiving Oczyesa had normal levels of IGF-1, compared with 38% (9 out of 24) of those given placebo.

What are the risks associated with Oczyesa?

For the full list of side effects and restrictions with Oczyesa, see the package leaflet.

The most common side effects with medicines containing octreotide (which may affect up to 1 in 10 people) include abdominal (belly) pain, constipation, flatulence (gas), nausea (feeling sick) and diarrhoea, headache, cholelithiasis (gallstones; hardened pieces of bile that form in the gallbladder), hyperglycaemia (high levels of blood sugar), and reactions at the injection site.

Why is Oczyesa authorised in the EU?

The European Medicines Agency considered that Oczyesa was effective at maintaining disease control, as assessed by normal IGF-1 levels, in patients with acromegaly. In addition, the medicine is available as pre-filled pens which patients can use themselves after training and can be stored at room temperature. The safety profile of Oczyesa was considered acceptable and comparable to the known safety profile of other somatostatin analogues.

Therefore, the Agency decided that the benefits of Oczyesa 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 Oczyesa?

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

As for all medicines, data on the use of Oczyesa are continuously monitored. Suspected side effects reported with Oczyesa are carefully evaluated and any necessary action taken to protect patients.

Other information about Oczyesa

Oczyesa received a marketing authorisation valid throughout the EU on 30 June 2025.

Further information on Oczyesa can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/oczyesa.

This overview was last updated in 05-2025.