EMA/781118/2022
EMEA/H/C/005826

Mycapssa (*octreotide*)

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

What is Mycapssa and what is it used for?

Mycapssa is a medicine used for the maintenance (long-term) treatment of acromegaly (a condition where the body produces too much growth hormone, leading to excessive growth of body tissue and bones, particularly of the hands, feet and face). Mycapssa can be used in adults who have previously responded to and tolerated treatment with other somatostatin analogues (synthetic versions of the hormone somatostatin).

Mycapssa is a 'hybrid medicine', meaning 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 Mycapssa is Sandostatin IR, which is a solution given as an injection or infusion (drip), whereas Mycapssa is a capsule given by mouth.

Acromegaly is rare, and Mycapssa was designated an 'orphan medicine' (a medicine used in rare diseases) on 5 August 2013. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations/EU3131170

Mycapssa contains the active substance octreotide.

How is Mycapssa used?

Mycapssa can only be obtained with a prescription.

It is available as capsules to be taken twice a day by mouth. Capsules should be taken at least two hours after eating, and patients should not eat for at least one hour after taking the medicine.

Mycapssa treatment may be started anytime after receiving the last somatostatin analogue injection and before the next planned injection. The starting dose of Mycapssa is 40 mg per day. Patients are then monitored by their treating doctor to check for signs and symptoms of their disease and measure levels of insulin-like growth factor 1 (IGF-1, a hormone which stimulates cell development, in particular of muscles, cartilage, bone, and certain organs). The dose of Mycapssa may be increased to a maximum of 80 mg per day to achieve disease control. Treatment may be stopped if levels of IGF-1 cannot be controlled at the highest dose or if the patient cannot tolerate treatment.

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How does Mycapssa work?

Acromegaly is a disease in which the pituitary gland (a small gland located at the base of the brain) produces too much growth hormone, in most cases because of pituitary adenoma (a non-cancerous tumour in the pituitary gland). The active substance in Mycapssa, octreotide, is a somatostatin analogue (a synthetic version of the hormone somatostatin). The medicine attaches to somatostatin receptors (targets) to lower the levels of growth hormone, thereby reducing disease symptoms.

What benefits of Mycapssa have been shown in studies?

The benefits of Mycapssa have been investigated in three main studies that assessed whether patients who controlled their disease with an injectable somatostatin analogue could maintain control of their disease after they were given Mycapssa capsules by mouth. Disease control was measured by comparing the levels of IGF-1 in their blood with levels seen in healthy people.

In the first study, 146 patients were first given Mycapssa for 26 weeks to determine an optimal dose to control their disease. Of these patients, 79.5% (116 out of 146) could sustainably maintain disease control with Mycapssa, and 63% (92 out of 146) of them continued the study. These patients then either continued treatment with Mycapssa or changed back to an injectable somatostatin analogue for 36 weeks. Of the patients treated with Mycapssa, 91% (50 out of 55) maintained control of their disease compared with 100% (37 patients) of those who were given an injectable somatostatin analogue.

In the second study, 56 patients received either Mycapssa or placebo (a dummy treatment). After 36 weeks of treatment, 57% (16 out of 28) of patients given Mycapssa and 18% (5 out of 28) of patients given placebo were able to keep their disease under control.

In the third study, patients treated with an injectable somatostatin analogue changed treatment to Mycapssa for 7 months, and around 65% (98 out of 151 patients) maintained control of their disease.

What are the risks associated with Mycapssa?

The most common side effects with Mycapssa (which may affect more than 1 in 10 people) are abdominal pain, diarrhoea, and nausea (feeling sick).

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

Why is Mycapssa authorised in the EU?

The European Medicines Agency considered that Mycapssa was as effective as injectable somatostatin analogues to maintain biochemical disease control in patients with acromegaly. The safety of Mycapssa was comparable to that seen with injectable somatostatin analogues and was considered acceptable. Therefore, the Agency decided that the benefits of Mycapssa 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 Mycapssa?

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

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

Other information about Mycapssa

Mycapssa received a marketing authorisation valid throughout the EU on 02 December 2022.

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

This overview was last updated in 12-2022.