15 September 2022
EMA/721412/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Mycapssa

octreotide

On 15 September 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Mycapssa[2], intended for the treatment of adult patients with acromegaly. The applicant for this medicinal product is Amryt Pharmaceuticals DAC.

Mycapssa will be available as a 20 mg gastro-resistant hard capsule. The active substance of Mycapssa is octreotide, a somatostatin analogue (ATC code: H01CB02). It inhibits pathologically increased secretion of growth hormone in patients with acromegaly.

The benefit of Mycapssa is its ability to maintain biochemical control of pathologically increased hormone secretion in patients with acromegaly after switching from an injectable form of octreotide. The most common side effects are abdominal pain, diarrhoea and nausea.

Mycapssa is a hybrid medicine[3] of Sandostatin IR which has been authorised in the EU since 06 Oct 1995. Mycapssa contains the same active substance as Sandostatin IR, but in contrast to Sandostatin IR it is administered orally in hard capsules.

Studies have demonstrated the satisfactory quality of Mycapssa.

The full indication is:

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

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

[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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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.