Report octreotide - Mycapssa®

Product & Mechanism of action	Authorized indications Licensing status	Essential therapeutic features	NHS impact
Substance: octreotide **Brand Name:** Mycapssa **Originator/licensee:** Amryt Pharmaceuticals DAC **Classification:** NCE **ATC code:** H01CB02 **Orphan Status:** **Eu:** Yes **Us:** Yes **Mechanism of action:** Octreotide is a somatostatin analogue. It inhibits pathologically increased secretion of GH in patients with acromegaly [1].	**Authorized Indication:** **EMA:** octreotide is indicated for maintenance treatment in adult patients with acromegaly who have responded to and tolerated treatment with somatostatin analogues [1]. **FDA:** octreotide is a somatostatin analog indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide [2]. **Route of administration:** os **Licensing status** **EU CHMP P.O. date:** 15/07/2022 **FDA M.A. date:** 26/06/2020 **EU Speed Approval Pathway:** No **FDA Speed Approval Pathway:** No --- **ABBREVIATIONS:** **AE:** adverse event **DPC:** double-blind pbo-controlled **GH**: growth hormone **Gi**: gastrointestinal **IGF-1**: insulin-like growth factor 1 **OLE**: open-label extension **OOC**: oral octreotide capsules **Pbo**: placebo **Pts**: patients **Q2W**: twice daily **SRLs**: somatostatin receptor ligands **TEAE**: treatment emergent adverse event **ULN**: upper limit of normal	**Summary of clinical EFFICACY:** CHIASMA OPTIMAL (NCT03252353) was a phase III, prospective, multicenter, randomized, double-blind, placebo-controlled study to evaluate efficacy and safety of octreotide in pts (aged 18 yrs or older) with acromegaly (n=56) who previously demonstrated biochemical control while receiving injectable SRLs. The primary efficacy endpoint was somatostatin dose-adjusted proportion of pts who maintain their biochemical response, defined as an IGF-1 levels less than or equal to the ULN at the end of 9 month of treatment (mean IGF-1 ≤ 1.0 x ULN; weeks 34 and 36]. Eligible pts were randomly assigned 1:1 to ooc (n=28) or pbo (n=28). Pts initiated treatment Q2W 1 month after their last injecton of somatostatin analogs. The starting dose was 40mg. Dose increase was allowed during dose titration to 60mg and to a maximal dose of 80mg until pts were deemed adequately controlled based on biochemical results and/or clinical judgement. Pts then maintained their target dose until end of treatment. 58% of pts treated with octreotide vs 19% of pts treated with pbo maintained their biochemical response [3]. **Summary of clinical SAFETY:** Of the 56 pts in the safety population, 55 (98.2%) experienced 1 or more TEAEs during the dpc period (oocs, 28 pts (100%); pbo, 27 pts (96.4%)]). Most of the TEAEs were assessed by the investigators as unrelated to the study drug. TEAEs with an incidence of 5% or more that were more common in the OOC group than in the pbo group were diarrhea, nausea, abdominal discomfort, vomiting, dyspepsia, blood glucose increased, sinusitis, osteoarthritis, cholelithiasis, urinary tract infection, large intestine polyp, and pain. All of the gi TEAEs reported in the OOC group were mild or moderate in intensity. AESIs that could be attribuited to acromegaly were observed more frequently in pts receiving pbo than those receiving OOCs. The most common AESIs observed were arthralgia, hyperhidrosis, headache, fatigue, carpal tunnel syndrome, and peripheral swelling. Of pts receiving oocs, 1(3.6%) experienced AEs of hypoglycemia, 3 (10.7%) reported blood glucose increase, and 1 (3.6%) reported hyperglycemia [3]. **Ongoing studies:** ● ***For the same indication:*** Yes [4]. ● ***For other indications:*** No **Discontinued studies (for the same indication):** No	**Cost of therapy:** Price is not available yet. **Epidemiology:** Acromegaly is a rare disease (10% of all pituitary adenomas), with a total prevalence between 2.8 and 13.7 cases/ 100,000 and an annual incidence between 0.2 and 1.1 cases/100,000 [5]. --- **POSSIBLE PLACE IN THERAPY** Lanreotide [6]. **OTHER INDICATIONS IN DEVELOPMENT** No **SAME INDICATION IN EARLIER LINE(S) OF TREATMENT:** No **OTHER DRUGS IN DEVELOPMENT for the SAME INDICATION** No *Service reorganization: No *Possible off label use: Yes --- **References:** [1].https://www.ema.europa.eu/en/medicines/human/summaries-opinion/mycapssa [2].https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/208232s000lbl.pdf [3].https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7470473/ [4]. https://adisinsight.springer.com/drugs/800032322 [5].https://www.associazionemediciendocrinologi.it/images/pubblicazioni/pos-stat/Position-acro2019-italiano.pdf [6].https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7942783/

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