

Mycapssa® (octreotide) - New orphan drug approval

- On June 26, 2020, <u>Chiasma announced</u> the FDA approval of Mycapssa (octreotide), for long-term
 maintenance treatment in acromegaly patients who have responded to and tolerated treatment with
 octreotide or lanreotide.
- Acromegaly is a rare chronic disease often caused by a benign pituitary tumor and characterized by excess production of growth hormone and insulin-like growth factor-1 hormone.
- Mycapssa is the first and only oral somatostatin analog approved by the FDA.
- Octreotide is also available generically as a <u>solution for injection</u>, as branded <u>Sandostatin[®] LAR</u>
 <u>Depot</u> powder for suspension for injection, and branded <u>Bynfezia[®]</u> pen injection.
 - These formulations of octreotide are approved for acromegaly, carcinoid tumors, and vasoactive intestinal peptide tumors.
- The efficacy of Mycapssa was established in a randomized, double-blind, placebo-controlled study in 56 patients with acromegaly. Patients received Mycapssa or placebo. The primary efficacy endpoint was somatostatin dose-adjusted proportion of patients who maintain their biochemical response, defined as an insulin-like growth factor 1 (IGF-1) levels less than or equal to the upper limit of normal (ULN) at the end of 9 months of treatment.
 - Overall, 58% of patients treated with Mycapssa vs. 19% of patients treated with placebo maintained their biochemical response.
- Warnings and precautions for Mycapssa include cholelithiasis and complications of cholelithiasis;
 hyperglycemia and hypoglycemia; thyroid function abnormalities; cardiac function abnormalities; and decreased vitamin B₁₂ levels and abnormal Schilling's tests.
- The most common adverse reactions (> 10%) with Mycapssa use were nausea, diarrhea, headache, arthralgia, asthenia, hyperhidrosis, peripheral swelling, blood glucose increased, vomiting, abdominal discomfort, dyspepsia, sinusitis, osteoarthritis.
- The recommended initial dose of Mycapssa is 40 mg daily, administered as 20 mg orally twice daily.
 The dosage should be titrated based on IGF-1 levels and patient's signs and symptoms. The dosage should be increased in increments of 20 mg daily.
 - For Mycapssa dosages of 60 mg daily, administer as 40 mg in the morning and 20 mg in the evening.
 - For Mycapssa dosages of 80 mg daily, administer as 40 mg twice daily.
 - The maximum recommended dosage of Mycapssa is 80 mg daily.
- Chiasma plans to launch Mycapssa in the fourth quarter 2020. Mycapssa will be available as 20 mg
 capsules.



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