RXADVANCE
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CLINICAL UPDATE

Brand Name	MYCAPSSA®
Generic Name	octreotide
Drug Manufacturer	Chiasma

Clinical Update

Clinical Update: MYCAPSSA® (octreotide) FDA Approved Capsules Delayed Release

FDA Approval Date: 6/26/2020

Overview

MYCAPSSA® is a somatostatin analog indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

Octreotide exerts pharmacologic actions similar to the natural hormone somatostatin, but is a more potent inhibitor of GH, glucagon, and insulin than somatostatin. Like somatostatin, it also suppresses luteinizing hormone (LH) response to gonadotropin-releasing hormone (GnRH), decreases splanchnic blood flow, and inhibits release of serotonin, gastrin, vasoactive intestinal peptide, secretin, motilin, and pancreatic polypeptide.

Efficacy

The efficacy of MYCAPSSA® was established in a 9 month, randomized, double-blind, placebo-controlled study (NCT03252353) that enrolled 56 patients with acromegaly. In the overall study population, 54% were female and the average age of patients was 55 years. 91% of patients were Caucasian, 5% Asian, 2% Black, and 2% Other. The percentage of patients with previous pituitary surgery was 88%. The baseline IGF-1 levels (the average of 2 assessments measured within 2 weeks of randomization) was 0.80 times ULN (range: 0.5–1.1 times ULN) in the patients treated with MYCAPSSA® and 0.84 times ULN (range: 0.3–1.1 times ULN) in patients treated with the placebo.

In this study, patients initiated MYCAPSSA® treatment twice daily 1 month after their last injection of somatostatin analogs. The starting dose was 40 mg (20 mg in the morning and 20 mg in the evening). Dose increase was allowed during dose titration to 60 mg (40 mg in the morning and 20 mg in the evening) and to a maximal dose of 80 mg daily (40 mg in the morning and 40 mg in the evening) until patients were deemed adequately controlled based on biochemical results and/or clinical judgement. Patients then maintained their target dose until end of treatment.

The primary efficacy endpoint was somatostatin dose-adjusted proportion of patients who maintain their biochemical response, defined as an IGF-1 levels less than or equal to the ULN at the end of 9 months of treatment. 58% of patients treated with MYCAPSSA® vs. 19% of patients treated with placebo maintained their biochemical response.

25% of patients treated with MYCAPSSA® required discontinuation of MYCAPSSA® and treatment with other somatostatin analogs at some point during the 9-month study. Criteria for somatostatin analog rescue were IGF-1 levels higher than 1.3 times ULN and exacerbation of acromegaly signs and symptoms on two consecutive assessments while treated for at least 2 weeks with 80 mg/day or other reasons such as adverse reactions or patient's decision.

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Dose & Administration

Take MYCAPSSA® orally with a glass of water on an empty stomach, at least 1 hour before a meal or at least 2 hours after a meal.

Initiate MYCAPSSA® at a dosage of 40 mg daily, administered as 20 mg orally twice daily.

Monitor insulin-like growth factor 1 (IGF-1) levels and patient's signs and symptoms every two weeks during the dose titration or as indicated.

Titrate the MYCAPSSA® dosage, based on IGF-1 levels and patient's signs and symptoms. Increase the dosage in increments of 20 mg.

The maximum recommended dosage is 80 mg daily.

Once the maintenance dosage of MYCAPSSA® is achieved, monitor IGF-1 levels and patient's signs and symptoms monthly or as indicated.

For patients with end-stage renal disease, initiate at a dosage of 20 mg orally once daily. Titrate and adjust the maintenance dosage based on IGF-1 levels, patient's signs and symptoms and tolerability.

DOSAGE FORM(S) & STENGTH(S):

Delayed-release capsules: 20 mg

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