



Dosing and Administration Guide

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INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

MYCAPSSA (octreotide) delayed-release capsules, for oral use, is a somatostatin analog indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

CONTRAINDICATIONS

Hypersensitivity to octreotide or any of the components of MYCAPSSA. Anaphylactoid reactions, including anaphylactic shock, have been reported in patients receiving octreotide.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.



Getting Patients Started on Daily Oral MYCAPSSA is Straightforward

Example dosing schedule:



Take MYCAPSSA on an empty stomach* twice daily with a glass of water



Morning dose:

Just after waking

Evening dose:

Right before bed

Each wallet of MYCAPSSA comes with 28 capsules. Each MYCAPSSA capsule is 20 mg.



^{*}One hour before or two hours after a meal

IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

The most common adverse reactions (incidence >10%) are nausea, diarrhea, headache, arthralgia, asthenia, hyperhidrosis, peripheral swelling, blood glucose increased, vomiting, abdominal discomfort, dyspepsia, sinusitis, and osteoarthritis.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

Starting and Optimizing MYCAPSSA

Example titration schedule:*



Week 1: Week 2-3: Week 4-5:

Start MYCAPSSA at 40 mg

Evaluate IGF-I, signs, and symptoms. Titrate MYCAPSSA to 60 mg as early as week 2-3 Evaluate IGF-I, signs, and symptoms. Titrate to 80 mg[†] as needed, as early as week 4-5

Once the maintenance dosage of MYCAPSSA is achieved, monitor IGF-I levels and acromegaly signs and symptoms monthly.

^{*}The example titration schedule above reflects the total daily dose of MYCAPSSA. Refer to the full Prescribing Information for a detailed dosing schedule.

[†] The maximum daily dose of MYCAPSSA is 80 mg.





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WARNINGS AND PRECAUTIONS

MYCAPSSA can cause problems with the gallbladder. Monitor patients periodically. Discontinue if complications of cholelithiasis are suspected.

Blood sugar, thyroid levels, and vitamin B₁₂ levels should be monitored and treated accordingly.

Bradycardia, arrhythmia, or conduction abnormalities may occur. Treatment with drugs that have bradycardia effects may need to be adjusted.

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DRUG INTERACTIONS

The following drugs require monitoring and possible dose adjustment when used with MYCAPSSA: cyclosporine, insulin, antidiabetic drugs, calcium channel blockers, beta blockers, lisinopril, digoxin, bromocriptine, and drugs mainly metabolized by CYP3A4. Counsel women taking an oral contraceptive to use an alternative non-hormonal method of contraception or a back-up method when taking MYCAPSSA.

Patients taking proton pump inhibitors, H2-receptor antagonists, or antacids concomitantly with MYCAPSSA may require increased dosages of MYCAPSSA.

PREGNANCY

Advise premenopausal females of the potential for an unintended pregnancy.

To report SUSPECTED ADVERSE REACTIONS, please contact Chiesi Farmaceutici S.p.A. at 1-888-661-9260 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

