Mycapssa®
(octreotide) capsules 20mg

Take Control with daily oral MYCAPSSA

Bonnie,
actual MYCAPSSA patient

The first and only oral SSA*

What is MYCAPSSA (octreotide) for?

MYCAPSSA (octreotide) delayed-release capsules is an oral prescription medicine used in the long-term maintenance treatment of acromegaly in people for whom initial treatment with octreotide or lanreotide has been effective and tolerated.

*Somatostatin analog.

Chiesi

For Important Safety Information, please see enclosed full Prescribing Information and Patient Information.

Goals of Acromegaly Medication Beyond Tumor Control

Hormone level control

Expert guidelines from the Endocrine Society recommend achieving the same IGF-I blood level as someone without acromegaly and growth hormone level of less than 1.0 µg/L.

Well-controlled hormone levels have been shown to:

- Improve mortality risk
- Improve comorbidities including:
  - — Respiratory disorders (such as sleep apnea)
  - — Skeletal complications (such as carpal tunnel syndrome)
  - — Cardiovascular conditions (such as hypertension)

It's essential to monitor IGF-I in a timely manner to identify any increased levels.

Symptom relief

Most common symptoms include:

- Joint pain
- Excessive sweating
- Brain fog/short-term memory loss
- Swelling of soft tissue
- Fatigue/weakness/tiredness
- Headache

Controlling symptoms is important because:

- They can interfere with daily life, including work and leisure activities, ultimately impacting quality of life

You may still experience symptoms even if your IGF-I levels are within normal range.

IGF-I, insulin-like growth factor-1

Possible Treatment Experience

Several recent studies looked at the burden associated with injectable SSAs* in people with acromegaly

Pain during injection

>80% of patients reported experiencing pain during injections.

Pain after injection

36% to 49% of patients reported injection-site pain lasting several days after injection.

Loss of independence

36% of patients felt a loss of independence due to chronic injections.

*SSAs, somatostatin analogs, including long-acting forms of octreotide or lanreotide.

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Introducing MYCAPSSA Delayed-Release Capsules

Proven efficacy and safety profile

Twice-daily oral capsule

MYCAPSSA is the oral version of octreotide, a medication you may already be familiar with.

IMPORTANT SAFETY INFORMATION

What is the most important safety information I should know?
MYCAPSSA can cause problems with the gallbladder. Tell your healthcare provider if you have any of these symptoms: sudden pain in your upper right stomach (abdomen) or right shoulder or between your shoulder blades; yellowing of your skin or the whites of your eyes; fever with chills; or nausea.

For additional Important Safety Information, please see enclosed full Prescribing Information and Patient Information.

IMPORTANT SAFETY INFORMATION (cont.)

What is the most important safety information I should know? (cont.)
MYCAPSSA may affect your blood sugar, thyroid hormone, or vitamin B_{12} levels. Tell your healthcare provider if you have any problems or conditions related to these. Your healthcare provider may monitor these levels during your treatment with MYCAPSSA.

Tell your healthcare provider if you have an irregular heartbeat.

Extensively Studied Oral Treatment

The safety and efficacy of MYCAPSSA was studied in:

3 clinical trials

329 people living with acromegaly

who previously responded to and tolerated injectable SSA treatment with octreotide or lanreotide.

The 2 main studies were:

Study name	Study length	Treatments compared	Outcome
OPTIMAL	9 months	MYCAPSSA vs placebo	• Established efficacy and safety profiles of MYCAPSSA • Led to the FDA approval of MYCAPSSA
MPOWERED	9 months	MYCAPSSA vs injectable SSA	• Demonstrated that MYCAPSSA maintained biochemical control*

FDA, US Food and Drug Administration; ULN, upper limit of normal.
*Primary endpoint of noninferiority assessment of the proportion of patients maintaining biochemical response (IGF-I <1.3 x ULN using time-weighted average) throughout the randomized controlled treatment phase.

IMPORTANT SAFETY INFORMATION (cont.)

Who should not use MYCAPSSA?
MYCAPSSA can cause a serious allergic reaction including anaphylactic shock. Stop taking MYCAPSSA right away and get emergency help if you have any of these symptoms: swelling of your tongue, throat, lips, eyes or face; trouble swallowing or breathing; severe itching of the skin with rash or raised bumps; feeling faint; chest pain; or rapid heartbeat.

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OPTIMAL Study Results

In the pivotal phase 3 trial, a majority of MYCAPSSA-treated patients maintained IGF-I control

56 patients with acromegaly participated in the main clinical study, which focused on safety and how MYCAPSSA works in patients. The following outcomes were reported at 9 months:

92% who responded to MYCAPSSA at 6 months, with IGF-I levels in the normal range, **continued to respond at 9 months.**

90% who completed the study on MYCAPSSA **chose to continue to manage their acromegaly with MYCAPSSA.**

IMPORTANT SAFETY INFORMATION (cont.)

Who should not use MYCAPSSA? (cont.)
Do not use MYCAPSSA if you are allergic to octreotide or any other ingredients in MYCAPSSA. If you need to know the ingredients, ask your healthcare provider or pharmacist.

If you have certain other medical conditions, you should use MYCAPSSA with caution. Tell your healthcare provider about all your medical conditions, especially the following: pregnancy or breastfeeding; liver disease; kidney disease; or difficulty in emptying bladder completely.

MPOWERED Study Results

Phase 3 trial further demonstrated that MYCAPSSA maintained biochemical control

92 patients who responded to MYCAPSSA* after 26 weeks were randomized to a 9-month controlled phase with continued treatment on MYCAPSSA or on their prior injectable therapy. The following outcomes were reported:

IGF-I levels
Demonstrated consistent control of hormone levels, as in other phase 3 studies

Acromegaly symptoms
Consistent control of several common symptoms

Breakthrough† symptoms
Patients treated with MYCAPSSA reported fewer breakthrough symptoms:

- **Before MYCAPSSA:** 25% of patients experienced breakthrough symptoms
- **After 26 weeks on MYCAPSSA treatment:** Only 7% of patients experienced breakthrough symptoms

*Data are representative of patients responding to both MYCAPSSA and injectable SSAs.
†Breakthrough symptoms defined as worsened at the end of treatment cycle.

Safety Profile of MYCAPSSA

In clinical studies, MYCAPSSA was shown to be generally well tolerated

MYCAPSSA can cause problems with the gallbladder (especially in those with a history of gallstones). MYCAPSSA may affect your blood sugar, thyroid hormone, and vitamin B_{12} levels.

The most common side effects of MYCAPSSA are:

- **headache**
- **nausea**
- **diarrhea**
- **joint pain**
- **weakness**
- **excessive sweating**

Talk to your healthcare provider if you have any side effect that bothers you or that does not go away.

You may report side effects to the FDA at 1-800-FDA-1088.

Stomach and gut issues were mostly mild to moderate and resolved on treatment

- Occurred mostly during the first 3 months of treatment
- Typically resolved in less than **2 weeks**

Do not stop taking MYCAPSSA before speaking with your doctor or pharmacist.

IMPORTANT SAFETY INFORMATION (cont.)

Who should not use MYCAPSSA? (cont.)
Women taking an oral contraceptive should use an alternative non-hormonal method of contraception or a back-up method when taking MYCAPSSA. Tell your healthcare provider about all the medicines you take. MYCAPSSA may affect the way other medicines work, and other medicines may affect how MYCAPSSA works.

For additional Important Safety Information, please see enclosed full Prescribing Information and Patient Information.

IMPORTANT SAFETY INFORMATION (cont.)

What are the possible side effects of MYCAPSSA?
The most common side effects are headache, joint pain, nausea, weakness, diarrhea, and sweating a lot.

Talk to your healthcare provider if you have any side effect that bothers you or that does not go away. You may report side effects to the FDA at 1-800-FDA-1088.

Keep MYCAPSSA and all medicines out of the reach of children.

Taking MYCAPSSA Is Straightforward

Take MYCAPSSA twice daily as directed by your doctor

Take your dose of MYCAPSSA twice daily, **morning and evening.**

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

*One hour before or 2 hours after a meal.

Each wallet of MYCAPSSA comes with 28 capsules.

Each MYCAPSSA capsule is 20 mg.

Keep MYCAPSSA and all medicines out of the reach of children.

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The Importance of Optimizing MYCAPSSA

Dose optimization

Your doctor may work with you to adjust your starting dose, depending on your IGF-I levels and your acromegaly signs and symptoms.

Ongoing monitoring

- Get your IGF-I level measured as directed
- Track your symptoms and let your doctor know if you notice any changes

Talk to your doctor to see if you are on the optimal dose of MYCAPSSA.

IMPORTANT SAFETY INFORMATION (cont.)

How should I take MYCAPSSA?
Do not take MYCAPSSA with food. MYCAPSSA should be taken with a glass of water on an empty stomach. Take MYCAPSSA at least 1 hour before a meal or at least 2 hours after a meal (for example, you could take your morning dose 1 hour before breakfast and your evening dose at bedtime).

For additional Important Safety Information, please see enclosed full Prescribing Information and Patient Information.

IMPORTANT SAFETY INFORMATION

What is the most important safety information I should know?
MYCAPSSA can cause problems with the gallbladder. Tell your healthcare provider if you have any of these symptoms: sudden pain in your upper right stomach (abdomen) or right shoulder or between your shoulder blades; yellowing of your skin or the whites of your eyes; fever with chills; or nausea.

Continuous Patient Support

Chiesi TOTAL care℠

Visit **chiesitotalcare.com** or
call **1-833-346-2277**

A single call to your dedicated Chiesi Total Care℠ team is all it takes, and you'll receive:

Individual support
from your Patient Service Coordinator to understand your medication and medical needs

Insurance assistance
so that you receive what you qualify for

Worry-free refills
A pharmacist is always available and medication is delivered right to your door

For additional Important Safety Information, please see enclosed full Prescribing Information and Patient Information.

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Help When You Need It

All eligible commercially insured patients can get MYCAPSSA for $0 out of pocket

$0 OUT OF POCKET*

Program eligibility:

- You are enrolled in the patient support program
- You have commercial insurance and a valid prescription for an FDA-approved indication for MYCAPSSA
- You are a resident of the United States or one of its territories

*Please refer to the full Terms and Conditions for additional eligibility requirements.

We're here to help
1-833-346-2277
(Monday-Friday, 7:00 AM-7:00 PM CST)
www.chiesitotalcare.com

Mycapssa®
(octreotide) capsules 20mg

Take Control With Daily Oral MYCAPSSA

- **First and only oral somatostatin analog (SSA)**
- **Consistent, proven control of your IGF-I levels**
- **Demonstrated decrease in breakthrough symptoms***
- **Generally well tolerated**

*Data are representative of patients responding to both MYCAPSSA and injectable SSAs.

Talk to your doctor about MYCAPSSA today.

www.mycapssa.com

For Important Safety Information, please see enclosed full Prescribing Information and Patient Information. Please contact Chiesi Farmaceutici S.p.A. at 1-888-661-9260 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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