



In the long-term treatment of acromegaly

MAKE YOUR MOVE

TO MYCAPSSA

**MYCAPSSA is the oral octreotide
that treats acromegaly all day,
every day.***

*When taken as directed.



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.

Please see Important Safety Information throughout and accompanying full Prescribing Information, including Patient Information.

Speak Up About Symptoms

Controlling Symptoms Is an Important Goal of Acromegaly Treatment

The goals of acromegaly treatments include:

-  **Hormone control**
(IGF-I and GH)
-  **Symptom relief**
-  **Tumor control**
-  **Management of other health conditions**

GH, growth hormone; IGF-I, insulin-like growth factor 1.

Check out the glossary on page 20.

You may still experience symptoms even if your IGF-I is under control. Possible symptoms may include:

-  **Fatigue**
-  **Headache**
-  **Joint Pain**
-  **Sweating**
-  **Swelling**

Use your voice

Remember, your healthcare team relies on you to keep them informed about your symptoms. Speak up and continue to tell your care team how you feel.

MYCAPSSA Is the Only Octreotide That's Taken Orally

MYCAPSSA Has Been Extensively Studied



Proven safe and effective



Oral medication taken twice a day

What is MYCAPSSA?

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




INDICATION

WHAT IS MYCAPSSA (octreotide) FOR?

MYCAPSSA 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. If these treatments are effective and your body is tolerating it, you may be eligible to take MYCAPSSA instead of the injections. Ask your doctor if this oral treatment is appropriate for you.

Please see Important Safety Information throughout and accompanying full Prescribing Information, including Patient Information.

MYCAPSSA was evaluated in 3 main studies:

|  OPTIMAL Study |  MPOWERED Study* |  Open-Label Study |
|---|---|---|
| 9-month study | 15-month study | 13-month study |
| 56 [†] participants | 146 [‡] participants | 155 participants |
| <ul style="list-style-type: none">• Focused on safety and effectiveness of MYCAPSSA vs placebo• Led to the FDA approval of MYCAPSSA | <ul style="list-style-type: none">• Focused on the effectiveness of MYCAPSSA vs injectable somatostatin analogs | <ul style="list-style-type: none">• Focused on safety and effectiveness of MYCAPSSA |

*The MPOWERED study was not powered to report noninferiority or superiority between arms for symptoms and patient-reported outcomes. Patients who enrolled did so with the understanding that they may receive MYCAPSSA. The enrolled population may have been enriched for those who were unsatisfied with injectable therapy.

FDA, US Food and Drug Administration.
[†]28 patients were randomized to receive MYCAPSSA.
[‡]146 patients total, of which 92 entered the randomized controlled phase.

These trials studied MYCAPSSA, the oral version of octreotide. Octreotide therapy has been studied for decades in thousands of people.



MYCAPSSA Controls IGF-I



Most Patients Treated With MYCAPSSA Kept IGF-I Under Control*

In the OPTIMAL Study:



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.**

ULN, upper limit of normal.

*IGF-I response was defined as an average of weeks 34 and 36 IGF-I $\leq 1.0 \times$ ULN ($P = .008$).

In the MPOWERED Study:



Almost all patients on MYCAPSSA **maintained control of IGF-I,[†]** similar to those treated with an injectable somatostatin analog.

[†]Biochemical control was defined as IGF-I $< 1.3 \times$ ULN using time-weighted average.

What is IGF-I?

IGF-I is a hormone that causes bones and tissue to grow. Your care team will keep a close eye on your IGF-I levels, but it's just one part of your care. Other things like symptoms are also important to consider when discussing treatment options.

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.

MYCAPSSA may affect your blood sugar, thyroid hormone, or vitamin B₁₂ 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.

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



MYCAPSSA Reduces Breakthrough Symptoms

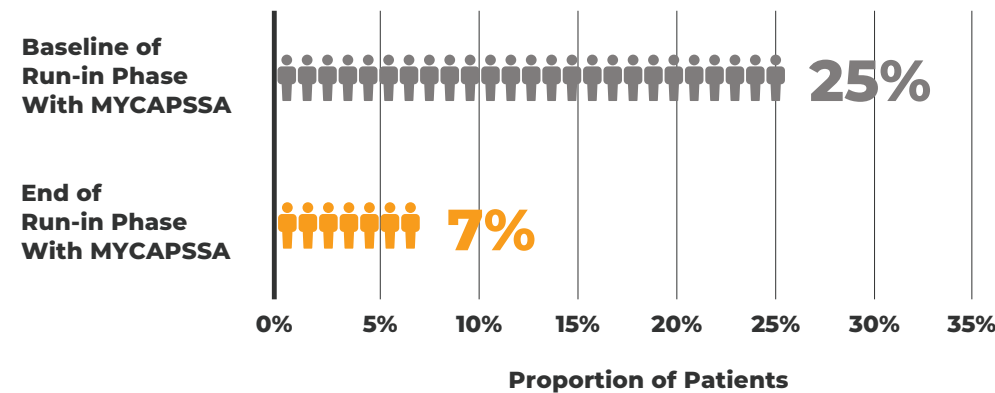


M In the MPOWERED Study:

Patients taking MYCAPSSA had a reduction in breakthrough symptoms:

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

Reported Breakthrough Symptoms



IMPORTANT SAFETY INFORMATION (cont.)

WHAT IS THE MOST IMPORTANT SAFETY INFORMATION I SHOULD KNOW? (cont).

MYCAPSSA may cause your body to have issues with absorbing dietary fats. Tell your healthcare provider if you have any new or worsening symptoms including fatty stools or stools with an oily appearance, changes in the color of your stools, loose stools, stomach (abdominal) bloating or weight loss.

“ Having MYCAPSSA as my treatment now has worked very well into my lifestyle. I love to travel and so I just take that wallet of pills, throw it in my suitcase, and go on with life.”

Becky – MYCAPSSA patient

Watch Becky's Story



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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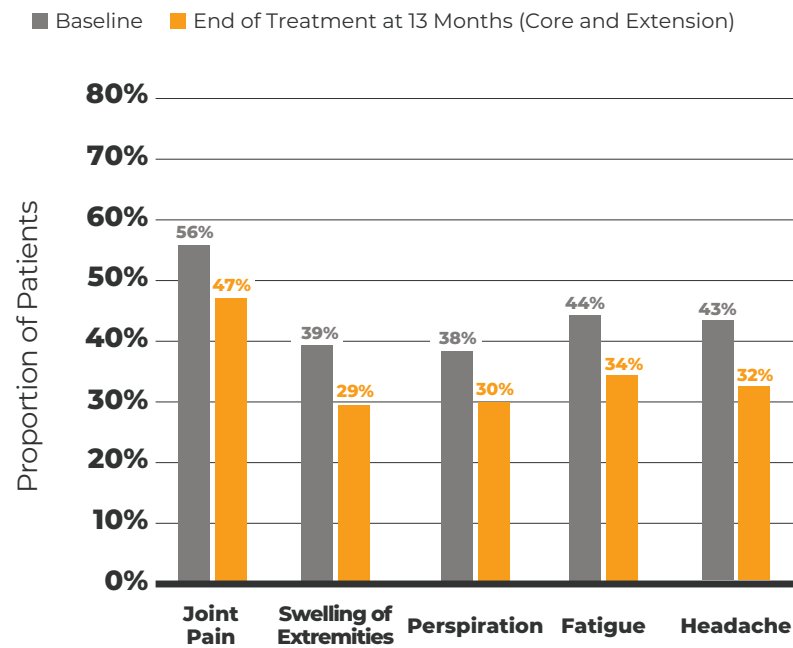


MYCAPSSA Controls Common Symptoms



Across Multiple Studies, MYCAPSSA-Treated Patients Demonstrated Consistent Symptom Control

OL Open-Label Study*



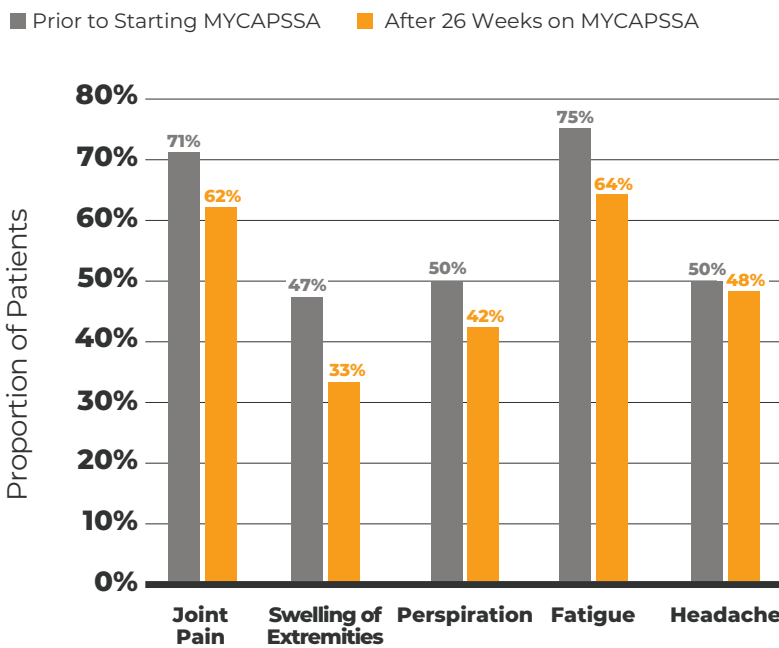
*Proportion of patients with active individual symptoms from baseline to end of treatment. Fixed-dose population (n=110). For patients not completing the core treatment period, the last assessment during the core treatment period was used. For patients not completing the extension treatment period, the last assessment during the extension treatment period was used.

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.

M MPOWERED Study†



†Proportion of patients with active individual symptoms at indicated timepoint during run-in phase.

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.

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



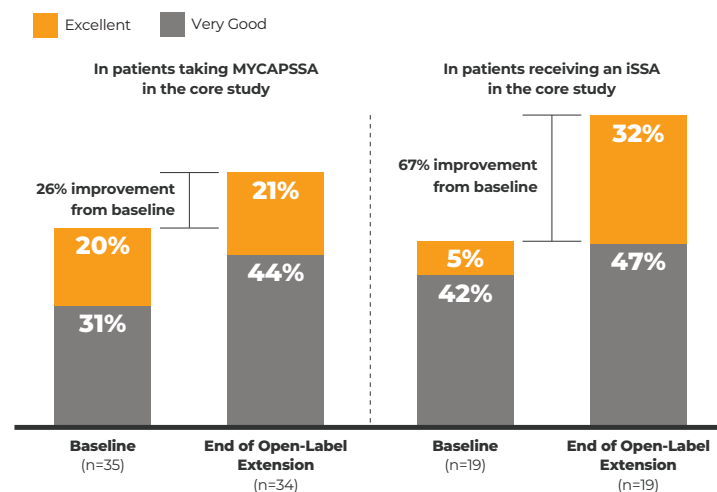
MYCAPSSA Controls Acromegaly, Long-Term

Safety Profile of MYCAPSSA



- Patients who finished the MPOWERED study were invited to participate in a long-term study extension
- All participants got MYCAPSSA regardless of what treatment they received in the MPOWERED study

Patients Reporting “Excellent” or “Very Good” Symptom Control



iSSA, injectable somatostatin analog.

Patients achieved long-term symptom control for up to an additional 3.5 years.

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 B₁₂ 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.



MYCAPSSA Treats Acromegaly and Its Symptoms All Day, Every Day

MYCAPSSA Provides Flexible Dosing



Take MYCAPSSA Twice Daily

- MYCAPSSA should be taken **1 hour before or 2 hours after meals**
- Establishing a habit can help you remember to take MYCAPSSA consistently

Here is an example:



First dose, just after waking

Second dose, midafternoon or right before bed

When your schedule changes day to day, you can adjust the timing of each dose:

- Does not need to be taken exactly 12 hours apart
- Does not need to be taken at the same time every day



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.

Storing MYCAPSSA

Once opened, MYCAPSSA wallets do not need to be refrigerated, and may be stored at room temperature for 30 days.

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.

You are encouraged to report negative side effects to Chiesi Farmaceutici S.p.A. at 1-888-661-9260 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Keep MYCAPSSA and all medicines out of the reach of children

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



Finding Your Optimal Dose of MYCAPSSA



“You’ve got to be your own advocate. Don’t suffer in silence... say what’s on your mind.”

Jim – MYCAPSSA patient



Watch Jim's Story

Just like with many other medications, your dose of MYCAPSSA might need to be adjusted depending on your IGF-I levels or acromegaly signs and symptoms.



Your doctor will monitor your IGF-I level regularly.



Keep track of symptoms and tell your care team how you feel.

Keep open lines of communication

Don't be afraid to speak up if you're not feeling well. Use the symptom tracker on pages 22 and 23 to keep track of how you've been feeling.

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).

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Continuous Patient Support

Help When You Need It



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

A single call to your dedicated Chiesi Total CareSM 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

All eligible commercially insured patients can get
MYCAPSSA for \$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 CT)
chiesitotalcare.com

Please see Important Safety Information
throughout and accompanying full
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Glossary



Baseline measurement:

A measurement that's taken at an early point in time, and then used to compare with measurements taken later on. For example, IGF-I may be measured before treatment (at baseline) and then after treatment to see if there was a change.

Breakthrough symptoms:

Any symptoms that get worse before your next scheduled dose of medication.

Growth hormone:

A protein made by the pituitary gland. Growth hormone, sometimes called GH, helps control growth of the body.

IGF-I:

A hormone that causes bones and tissue to grow. IGF-I works with growth hormone in the body. Growth hormone levels may change throughout the day depending on what you eat and how active you are, but IGF-I levels remain stable. So, an IGF-I test is a useful way to find out if the body is making a normal amount of growth hormone.

Octreotide:

Octreotide is a medication that treats high levels of the growth hormone caused by acromegaly. Octreotide therapy has been studied for decades in thousands of people.

Placebo:

An inactive substance that may be used in clinical testing. The effects of the placebo are compared to the effects of the medicine being tested. Participants who receive a placebo are called the control group.

Somatostatin analog:

A medicine that helps prevent the body from producing too many hormones, including growth hormone.

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INDICATION AND IMPORTANT SAFETY INFORMATION

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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.

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

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).



Track Your Symptoms

Use this space to keep track of symptoms. Write down any symptoms you experience including fatigue, headaches, joint pain, sweating, or swelling. Share this information with your care team and let them know how you've been feeling.

Date: _____

Today I felt: _____

On a scale from 1 to 10, I would rate it a: _____

Date: _____

Today I felt: _____

On a scale from 1 to 10, I would rate it a: _____

Date: _____

Today I felt: _____

On a scale from 1 to 10, I would rate it a: _____

Date: _____

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Today I felt: _____

On a scale from 1 to 10, I would rate it a: _____

Date: _____

Today I felt: _____

On a scale from 1 to 10, I would rate it a: _____

Date: _____

Today I felt: _____

On a scale from 1 to 10, I would rate it a: _____

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Take Control With MYCAPSSA



Consistent, proven **control of IGF-I levels and symptoms, with a decrease in breakthrough symptoms**



Generally **well tolerated** with no chance of injection-related reactions



Twice-daily dosing that treats acromegaly and its symptoms **all day, every day**



Continuous and comprehensive patient support with Chiesi Total CareSM



Supported by more than **35 years of real-world clinical experience** with octreotide



Visit mycapssa.com and sign up for more information.

For Important Safety Information, please see enclosed full Prescribing Information and Patient Information. You are encouraged to report negative side effects to 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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PP-RA-00245 V1.0



Mycapssa[®]
(octreotide) capsules
20mg