

New directions in acromegaly

The latest information
about your condition
and treatment options

Somatuline[®] Depot
(lanreotide) Injection



Understanding acromegaly

Acromegaly is a rare condition, with three to four new cases per year occurring for every million people.¹ Since its progression is slow and subtle, acromegaly frequently goes undiagnosed for years.²

Without treatment, acromegaly can affect your long-term health.¹ Fortunately, acromegaly can be treated successfully. However, to receive the full benefits of therapy, you should begin treatment as soon as possible.

After reading the following information about acromegaly and its treatment, please talk with your healthcare provider if you have any questions.

What is acromegaly?

Acromegaly occurs when too much growth hormone (GH) is released into the blood by the pituitary gland, located at the base of your brain.¹ Once released, GH is distributed by the blood throughout the body, where it affects growth and development, as well as your energy levels and sense of well-being.

GH also stimulates production of another hormone called insulin-like growth factor-1 (IGF-1), which helps control the growth of skin, connective tissue, cartilage, bone, organs, and nearly every other type of tissue in the body.

In 95% of cases, acromegaly is caused by a benign tumor in the pituitary gland.¹

What are the symptoms of acromegaly?

Because too much GH and IGF-1 can stimulate an overgrowth of tissue, acromegaly affects many different parts of the body, including your bones, joints, muscles, and internal organs.^{1,3}

As a result, acromegaly causes many symptoms, which range from joint pain, excessive sweating, headaches, and visual problems to depression, heart disease, and diabetes.¹ Over time, untreated acromegaly can change your facial features and enlarge your hands and feet. If left untreated, symptoms can become progressively worse. Fortunately, lowering GH and IGF-1 levels can make many of the symptoms subside.³

How is acromegaly diagnosed?

There's an easy blood test to confirm if you have acromegaly. It measures your IGF-1 level. People with acromegaly almost always have a high IGF-1 level in the blood because of too much GH.¹

Another way to test for acromegaly is to measure your GH level after drinking sugar water. This is called an oral glucose tolerance test.¹ Normally, the sugar water will make the pituitary gland stop producing GH. However, a pituitary tumor will not stop producing GH. This is why GH levels in the blood do not change after an oral glucose tolerance test in people with acromegaly.

Finally, if there is a pituitary tumor, it may show up on a magnetic resonance imaging (MRI) scan of the pituitary gland.³



Somatuline[®] Depot (lanreotide) Injection is an injectable medicine used for the long-term treatment of patients with acromegaly when surgery or radiotherapy has not worked well enough, or for patients who are not able to have surgery or radiotherapy.

Like all other medications, Somatuline[®] Depot can cause side effects. The most common include stomach and intestinal problems (diarrhea, abdominal

pain, or nausea), injection-site reactions (pain, itching, or a lump at the injection site), and gallbladder problems (cholelithiasis). Tell your doctor right away if you get severe pain in the right upper area of your stomach along with nausea and vomiting. These could be symptoms of a serious gallbladder problem (cholelithiasis).

How is acromegaly treated?

The goal of treatment for acromegaly is to lower GH and IGF-1 levels until they are normal, remove the tumor or reduce its size, and make the symptoms subside.¹ This can be done through surgery, by radiation treatment on the pituitary tumor, or with medicines.

Surgery

Surgery, the first form of treatment, is often effective in reducing hormone levels.¹ If the pituitary tumor is completely removed, the patient is cured. However, this is not always possible, especially for larger tumors. For these patients, additional therapy after surgery is often needed to normalize GH and IGF-1 levels.^{1,3}

Radiation

Radiation therapy is usually used after surgery has occurred and in patients who cannot be treated with medicines. While it also offers a permanent solution, it takes an average of seven years for radiation therapy to have its full effect.³ Also, there is usually a loss of normal pituitary function, requiring hormone replacement.^{1,3} Studies suggest that radiosurgery, a type of radiation that uses focused gamma rays, may be more effective and less likely to cause unwanted side effects than conventional radiation.¹

Medicines

There are three types of medicines available for the treatment of acromegaly. While they help manage the disorder, they do not cure it, so patients continue taking these medicines throughout their lives.

- **Somatostatin analogs** lower the GH level in the bloodstream by acting on GH-secreting cells in the pituitary. These medicines are used when GH and IGF-1 levels have not dropped to normal levels after surgery or radiation therapy.¹ They may also be the first choice for treatment in patients who may not be candidates for surgery or radiation.^{1,3} There are two long-acting somatostatin analogs that need to be taken only once every 28 days.^{4,5} Both are administered by injection, one of which is Somatuline® Depot (lanreotide) Injection. It is the only one that's injected under the skin; the other one is injected into the muscle.^{4,5}
- **GH receptor antagonists** are drugs that don't suppress the production of GH. Instead, they block the effect of GH once it is in the blood. Ultimately, this lowers the IGF-1 level (but not the GH level).¹ There's only one GH receptor antagonist available. It requires daily subcutaneous injections and is typically used in patients who have not responded to or who cannot take a somatostatin analog.¹
- **Dopamine agonists** work on dopamine receptors to slow down the release of GH from the tumor. However, they are generally less effective than somatostatin analogs at reducing GH and IGF-1 levels, and less effective than GH receptor antagonists at reducing IGF-1 levels. However, in specific patients, dopamine agonists can be helpful.³

What is Somatuline® Depot?

If your doctor has prescribed Somatuline® Depot for you, he or she has prescribed the newest treatment for acromegaly that is available in the United States. Somatuline® Depot is a patient-friendly option that has been proven to provide long-lasting, consistent control of GH and IGF-1 levels in medical studies.⁴



Other side effects include a low heart rate, high blood pressure, and other heart problems. Tell your doctor if you have a history of heart problems. Somatuline® Depot can cause a change in blood sugar levels. If you have diabetes, carefully follow your doctor's instructions for monitoring your blood sugar levels. This list of side effects is incomplete; your healthcare professional can discuss with you a more complete list of side effects that may occur when taking Somatuline® Depot.

How often will I have to take Somatuline® Depot?

You only need to take Somatuline® Depot (lanreotide) Injection once every four weeks.⁴ Once you have received your first deep subcutaneous injection of Somatuline® Depot, it takes only 24 hours for Somatuline® Depot to begin normalizing GH and IGF-1 levels.

Depending on your GH and IGF-1 levels, your doctor may eventually increase or reduce your dose so it's just right for you.

How is Somatuline® Depot given?

Somatuline® Depot is the only long-acting somatostatin analog that comes in a ready-to-use, prefilled syringe. This means there's no need to mix any of the ingredients before a Somatuline® Depot injection.⁴

Injecting Somatuline® Depot is simple. After removing Somatuline® Depot from the refrigerator 30 minutes ahead of time, it is given as a deep subcutaneous injection in the top, outside quadrant of the buttock. Your doctor will decide and/or supervise who administers the injection.

Will it hurt when I receive an injection?

Most patients want to know how long the needle is before receiving an injection. Fortunately, the Somatuline® Depot prefilled syringe is designed with patients in mind. The syringe has a shorter needle than the one used to inject Sandostatin LAR® Depot.^{4,5} Also, Somatuline® Depot requires 80% less fluid to be injected⁴⁻⁶ and is injected under the skin instead of into the muscle. These patient-friendly features may help reduce any temporary discomfort that can occur at the injection site.

A simply effective way to go

Tell your doctor if you take insulin or other diabetes medicines these may need to be changed in order to control your blood sugar while taking Somatuline® Depot. Also tell your doctor if you take cyclosporine (Gengraf®, Neoral®, Sandimmune®), bromocriptine (Parlodel®), or medicines that lower your heart rate such as beta blockers. Always talk to your doctor before starting any new medications.

Are there any possible side effects?

Somatostatin analogs as a class of drugs are well tolerated, and so is Somatuline® Depot. Somatuline® Depot was administered to more than 6,000 patients in 2006.⁷

Like all other medications, Somatuline® Depot can cause side effects. The most common are stomach and intestinal problems. Sometimes, skin reactions, such as pain, itching, or a lump may occur at the injection site. Gallbladder problems can also occur, so tell your doctor if you get severe pain in the right upper area of your stomach along with nausea and vomiting.⁴

Is Somatuline® Depot covered?

Somatuline® Depot—a recognized medical advancement for acromegaly—is available through leading specialty pharmacies and will be covered by most insurance companies.

A convenient reimbursement hotline, TerciCareSM, will help you determine your copay and find out where you can get the product.
Just call 1-866-TERCICA (1-866-837-2422).

For further information about acromegaly or Somatuline® Depot, please contact your healthcare provider.

Somatuline® Depot
(lanreotide) Injection  *A simply effective way to go*



Please see the Patient Information inside this brochure or visit www.somatulinedepot.com for additional important information.

Somatuline[®] Depot (lanreotide) Injection



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