

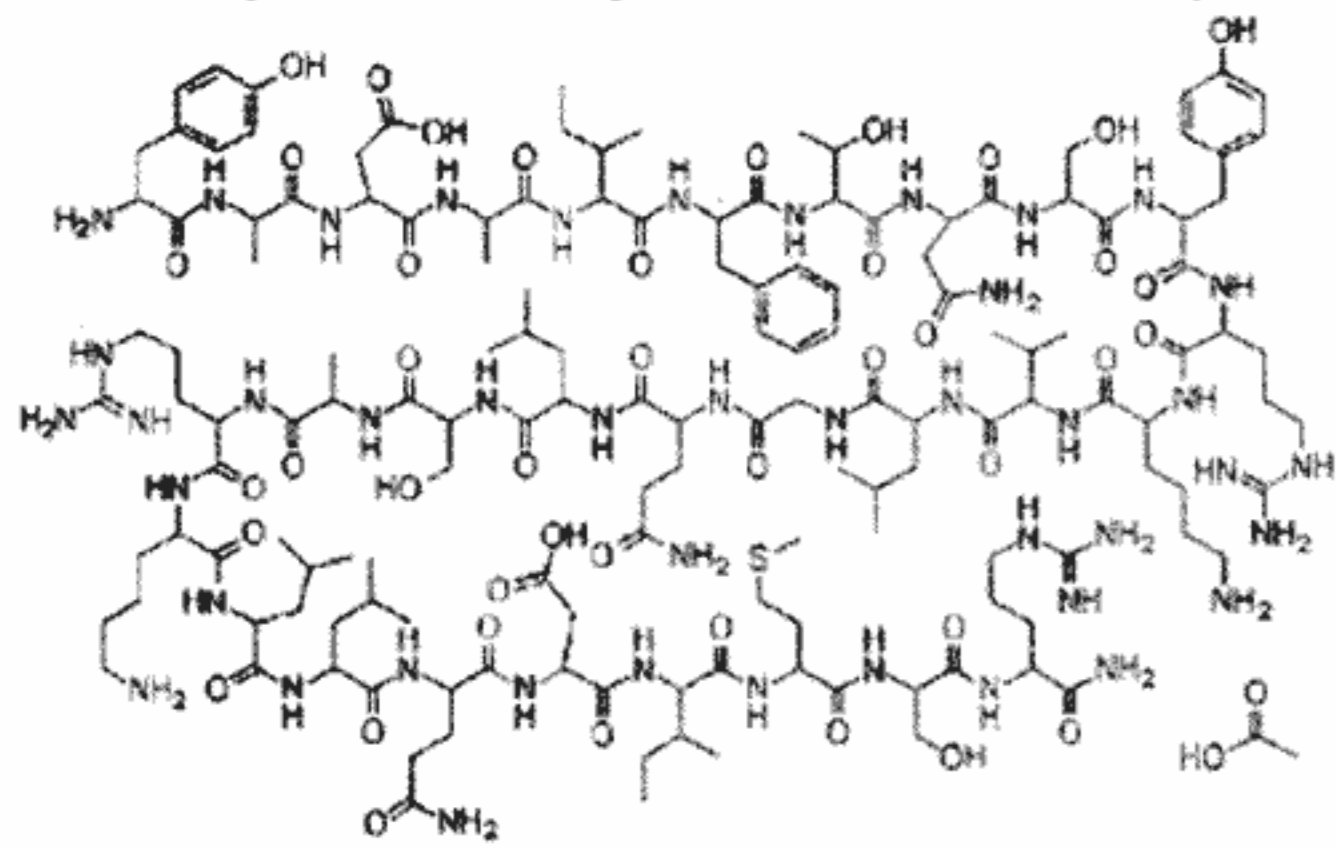
SERMORELIN

2mg/ml

Alley

1. Description

Sermorelin is a parenteral drug used as a Growth Hormone Releasing Hormone (GHRH). This synthetic, 29-amino acid polypeptide is the amino-terminal segment of the naturally occurring human growth hormone releasing hormone (GHRH) and consists of 44 amino acid residues. Sermorelin appears to be equivalent to endogenous GHRH in its ability to stimulate growth hormone secretion in humans.



Tyr-Ala-Asp-Ala-Ile-Phe-Thr-Asn-Ser-Tyr-Arg-Lys-Val-Leu-Gly-Gln-Leu-Ser-Ala-Arg-Lys-Leu-Leu-Gln-Asp-Ile-Met-Ser-Arg-NH₂

Compared to human Growth Hormone (HG), Sermorelin Acetate is a growth hormone secretagogue, which means that it stimulates the pituitary gland to produce and secrete growth hormone.

Molecular Formula: C₁₄₉H₂₄₆N₄₄O₄₂S

Molecular Weight: 3.358

CAS No.: 86168-78-7

Sequence: H-Tyr-Ala-Asp-Ala-Ile-Phe-Thr-Asn-Ser-Tyr-Arg-Lys-Val-Leu-Gly-Gln-Leu-Ser-Ala-Arg-Lys-Leu-Leu-Gln-Asp-Ile-Met-Ser-Arg-NH₂

Other names: Sermorelin Acetate Hydrate, GRF 1-29 NH₂

Sermorelin is a sterile, non-pyrogenic, white lyophilized powder intended for subcutaneous or intramuscular injection, after reconstitution with sterile Water for Injection (0,3% m-Cresol).

2. Mechanism of action

Sermorelin is a "growth hormone-releasing hormone" (GHRH). It stimulates production of increased amounts of the body's own natural human growth hormone. It is a truncated analog of a growth hormone releasing factor (GRF 1-44) that is naturally produced by the brain to stimulate pituitary production and the body's natural secretion of human growth hormone. The increased volume of Human Growth Hormone (rHG) produced by the pituitary causes an increase in the production of Insulin-Like Growth Factor-1 (IGF-1) resulting in the benefits of treatment provided to the adult patient.

Sermorelin benefits

- Increases the development of lean body mass through the development of new muscle cells
- Reduces body fat through lipolysis
- Increases energy and vitality
- Increases strength
- Increases endurance
- Accelerates healing from wounds or surgery
- Strengthens the heart
- Enhances the immune system
- Increases IGF-1 production
- Improves sleep quality
- Increases calcium retention, and strengthens and increases the mineralization of bone or bone density.

- Increases protein synthesis and stimulates the growth of all internal organs except the brain.
- Plays a role in fuel homeostasis.
- Reduces liver uptake of glucose, an effect that opposes that of insulin.
- Promotes liver glucogenesis.
- Contributes to the maintenance and function of pancreatic islets.

Sermorelin Acetate growth hormone releasing hormone therapy is considered one medical means of reversing the effects of aging in adults deficient in growth hormone because of the benefits resulting from the increased stimulation and secretion of human growth hormone by the pituitary gland.

3. Adverse reactions

The most common side effects with Sermorelin include local injection reactions (occurring in about 16%; pain, swelling or redness), but discontinuation of therapy is rare. Other treatment-related adverse reactions with occurrence rates of less than 1% include headache, flushing, dysphagia, dizziness, hyperactivity, somnolence and urticaria. The following side effects may occur with IV diagnostic use: transient warmth or flushing of the face; injection site reactions (pain, redness or swelling); nausea/vomiting; headache; dysgeusia; pallor; chest tightness (unspecified). Heart rate/blood pressure changes may occur with inadvertent over dosage. Antibody formation to Sermorelin has been reported frequently after chronic SC administration of large doses. The clinical significance is unknown, but antibodies do not appear to affect growth or appear to be related to a specific ADR profile. No generalized allergic reactions have been reported. A temporary allergic reaction described as severe redness, swelling and urticaria at the injection sites has been reported in one patient who developed antibodies. Single doses (like in diagnostic use) are unlikely to result in hypersensitivity reactions.

Patients should seek medical attention for suspected allergic reactions.

4. Contraindications/Precautions

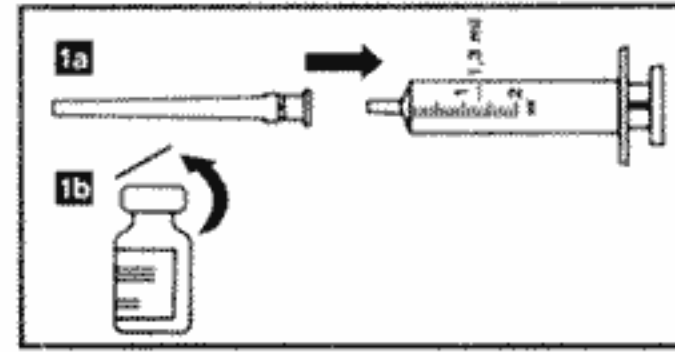
Contraindications: Hypersensitivity to Sermorelin or any of the components of the injection.

Precautions include:

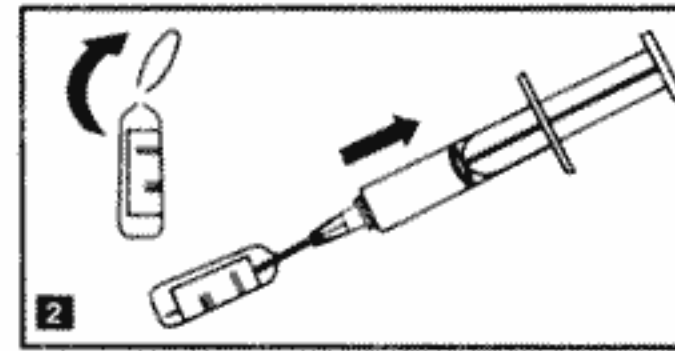
- Elderly: Clinical studies of Sermorelin diagnostic did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range.
- Hypothyroidism: Untreated hypothyroidism can jeopardize the response to Sermorelin. Thyroid hormone determinations should be performed before the initiation and during therapy. Thyroid hormone replacement therapy should be initiated when indicated.
- Intracranial lesions: Patients with GH deficiency secondary to an intracranial lesion were not studied in clinical trials; Sermorelin treatment is not recommended in such patients.
- Obesity, hyperglycemia or hyperlipidemia: Subnormal GH responses have been seen in obesity and hyperglycemia, and in patients with elevated plasma fatty acids.
- Pregnancy and Lactation: FDA pregnancy risk category C. Exercise caution during lactation; it is not known if this drug is excreted in breast milk.

5. Instructions for reconstitution

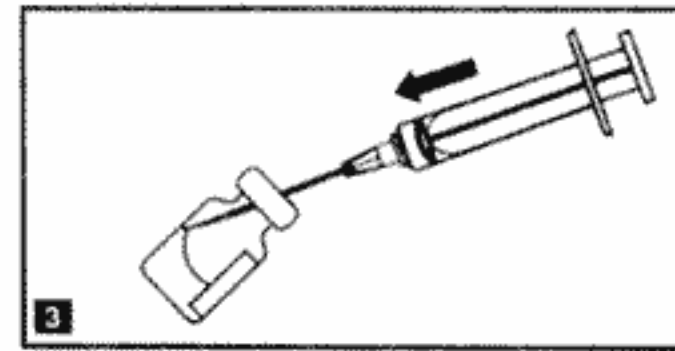
Powder must be dissolved only with the solvent provided.



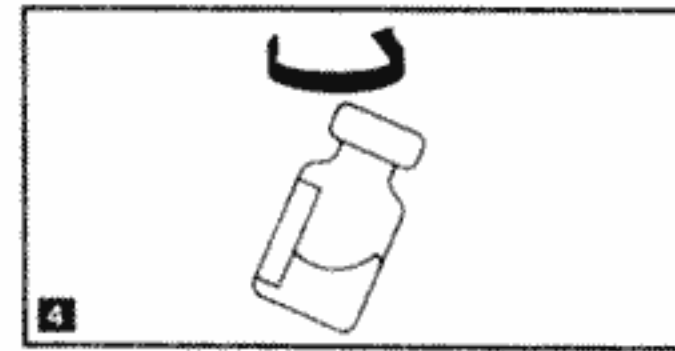
- 1a. Apply the needle to the syringe**
1b. Remove the plastic cover from the vial



- 2. Break the top of the ampoule containing the solvent. Remove the plastic cover of the needle. Make sure the needle is well applied to the syringe. Slowly absorb all the solvent.**



- 3. Inject all the solvent to the vial. This will create a 2mg/ml solution. To prevent foaming, the solvent should be injected into the vial by aiming the stream of liquid against the glass wall.**



- 4. Following reconstitution, the vial should be swirled with a GENTLE rotary motion until the contents are completely dissolved. DO NOT SHAKE.** The resulting solution should be clear and colorless, without particulate matter.

After reconstitution, the vial contains 1 ml liquid and 2mg Sermorelin. That means 2000mcg/ml. For example one injection with 100mcg Sermorelin needs 0,05ml (or 5 units on Insulin Syringe). One injection with 60mcg needs 0,03ml (or 3 units on Insulin Syringe).

6. Dosage

A dosage of 200-300 mcg Sermorelin once daily at bedtime by subcutaneous injection is recommended. It is also recommended that subcutaneous injection sites be periodically rotated.

7. Storage

- This product can be used not more than 3 years from the production date (see box)
- After reconstitution, may be stored for a maximum of 14 days in a refrigerator at 2°C - 8°C.
- Store vials in an upright position.
- Store in a refrigerator (2°C - 8°C). Keep in the outer carton in order to protect from light.
- For one month can be stored at room temperature.

THIS PRODUCT IS INTENDED FOR RESEARCH PURPOSES ONLY