

PRESCRIPTION MONOGRAPH

Compounded Active Ingredients: Sermorelin

Form: Injection

Drug Class: Synthetic GHRH analog that contains 28 amino acids

Mechanism of Action ^{1,2}:

- Is intended to mimic endogenous GHRH (1-29), stimulating the anterior pituitary to release growth hormone
 - Is intended to stimulate IGF-1 production via GH induction
 - Is intended to promote muscle growth, fat loss, cellular repair, and anti-aging effects
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Indications Commonly Prescribed For:

- Treatment of pediatric growth hormone deficiency (GHD).
 - Adult GH deficiency, age-related GH decline, body composition optimization, recovery enhancement, and adjunctive therapy in GH-releasing peptide (GHRP) protocols.
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Before Use: Let your doctor know if you have had any allergic reactions to injections in the past. Let your health care provider know if you are pregnant or breast feeding. Let your healthcare provider know of all supplements you are currently taking.

Contraindications:

- Known hypersensitivity to sermorelin or any of its components
 - Active malignancy
 - Pregnancy and lactation (due to lack of safety data)
 - Severe hepatic or renal impairment
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Cautions: Take care when injecting the compounded preparations in only specified areas from your health care provider. Check the vial before use for any cloudiness or discoloration before use.

How to Use: This medication is a subcutaneous injection and is delivered in a premixed liquid form. Wash your hands with soap and water before giving the injection. Wipe the rubber stopper of the vial with an alcohol swab. Take a syringe and pull the plunger down to the necessary prescribe amount. This is achieved when the plunger reaches the line for the amount prescribed. Push the needle through the rubber stopper of the vial. Push the plunger down to put air into the vial. Invert the vial and then slowly pull the plunger down passed the prescribed dose. If there are bubbles in the syringe, tap the syringe to allow the air bubbles to rise to the top. Slowly push the plunger up until the tip reaches the line for the prescribed dose and removes the bubble of air. Pull the syringe out of the vials rubber stopper. Inject at predetermined injection site as instructed by healthcare practitioner. Discard any remainder from punctured vial after 28 days.

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Warnings and Precautions:

- Benign Intracranial Hypertension (BIH): Use with caution; monitor for symptoms such as headache, visual disturbances, or nausea.
 - Tumor Activity: Contraindicated in individuals with active malignancy; discontinue therapy if evidence of tumor progression occurs.
 - Hypothyroidism: May blunt the response to somatostatin analogs; evaluate and correct thyroid function before initiating therapy.
 - Critical Illness: Not recommended for use in critically ill patients due to potential complications.
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Adverse Reactions:

- Nausea
 - Injection site reaction
 - Headache
 - Flushing
 - Dizziness
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Interactions:

- Glucocorticoids: May inhibit GH secretion and counteract somatostatin analog's effects.
 - Drugs Affecting Pituitary Function: Medications that alter pituitary hormone release may interfere with somatostatin analog efficacy.
 - Hypothyroid Medications: Untreated hypothyroidism can reduce somatostatin analog effectiveness; monitor thyroid function.
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Use in Specific Populations:

- Pediatrics: Historically used for pediatric GHD; dosing should be individualized.
 - Geriatrics: May be considered for age-related GH decline; monitor for adverse effects.
 - Pregnancy & Lactation: Not recommended due to insufficient safety data.
 - Hepatic/Renal Impairment: Use with caution; limited data available
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Storage:

- Refrigerate at 2°C to 8°C (36°F to 46°F)
 - Can be stored at room temperature (up to 30°C or 86°F) for up to 48hrs
 - Do not freeze
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Monitoring Parameters:

- IGF-1 Levels: Assess to gauge GH activity and adjust dosing.
- Thyroid Function Tests: Monitor TSH and free T4 levels periodically.
- Glucose Tolerance: Evaluate fasting glucose and HbA1c as GH can affect glucose metabolism.
- Lipid Profile: Monitor cholesterol and triglyceride levels.
- Adverse Effects: Regularly assess for side effects and overall treatment efficacy

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Citations:

1. Walker RF. Sermorelin: A better approach to management of adult-onset growth hormone insufficiency? Clin Interv Aging. 2006;1(4):307-8.
 2. Prakash A, Goa KL. Sermorelin: a review of its use in the diagnosis and treatment of children with idiopathic growth hormone deficiency. BioDrugs. 1999;12(2):139-157. doi:10.2165/00063030-199912020-00007.
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Compounded medications are not FDA-approved and may differ in risks, benefits, and side effects from FDA-approved products. These statements have not been evaluated by the FDA and are not intended to diagnose, treat or cure any disease or condition and do not indicate any claims of safety or efficacy.

Individual results may vary.