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PERSONALIZED MEDICINE

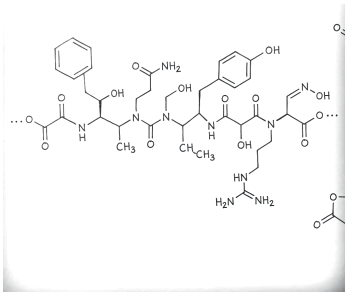
CLINICAL MONOGRAPH · AVAILABLE NOW

Sermorelin

GHRH analog with longstanding 503A history

Sermorelin is a 29-amino-acid peptide that copies the active end of the body's natural growth hormone-releasing hormone (GHRH). When injected subcutaneously, it tells the pituitary gland to release the patient's own growth hormone in pulses rather than replacing growth hormone directly. The FDA approved a manufactured sermorelin product called Geref in the 1990s, first as a diagnostic test, then as a treatment for children with idiopathic growth hormone deficiency. The manufacturer withdrew Geref from the U.S. market in 2008 for commercial reasons, not safety [fda_label_geref]. There is no FDA-approved sermorelin product available in the United States today.

Compounded sermorelin under 503A is prepared on patient-specific prescriptions for individual patients. The published evidence for sermorelin is strongest in pediatric growth hormone deficiency [grunt1995, neyzi1993] and as a diagnostic stimulus for the GHRH-arginine test in adult GH deficiency [molitch2011, yuen2019] [fda_label_geref]. Evidence for adult treatment and anti-aging use is weaker, short studies in older adults show modest changes in IGF-1 and body composition [khorram1997_may, vittone1997], but the largest systematic review of growth hormone in healthy older adults [liu2007] found no functional benefit and more adverse events. Sermorelin is not a fountain of youth. RonanRx compounds sermorelin only with documented clinical context and never as a direct-to-consumer anti-aging product.



EVIDENCE POSTURE WELL STUDIED EMERGING REVIEWED **2026-05-11**

State-licensed 503A | Pharmacist reviewed | Doctor led | Cold-chain ready | Patient choice preserved

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FOR CLINICIANS

Sermorelin acetate is GRF(1-29)-NH2, the N-terminal 29-residue fragment of human GHRH (1-44) and the shortest sequence that retains full GHRH-receptor agonist activity at the pituitary somatotrope [fda_label_geref]. Mechanism: sermorelin binds the pituitary GHRH receptor and stimulates pulsatile endogenous growth hormone secretion, with a downstream IGF-1 rise that follows the chronicity and amplitude of dosing [thorner1986, corpas1992] [prakash1999]. Plasma half-life after subcutaneous administration is short, minutes, but the pharmacodynamic GH response is durable enough to support nightly dosing, and continued nightly subcutaneous dosing in adults has been documented to raise mean overnight GH concentration, raise IGF-1 to mid-normal-young-adult range, and produce small changes in body composition.

Regulatory history: Geref (sermorelin acetate, Serono) was FDA-approved in 1990 as a diagnostic stimulus for GH-axis evaluation, and an extended dosing form was approved in 1997 for the long-term treatment of idiopathic GH deficiency in children with growth failure [fda_label_geref] [chen1993; grunt1995]. Pediatric efficacy in idiopathic GHD is supported by controlled trials and large open-label experience demonstrating growth velocity gains comparable to recombinant GH in selected responders. Geref was withdrawn from the U.S. market in 2008 for commercial reasons unrelated to safety; no FDA-approved sermorelin product is available in the U.S. today. The principal contemporary use of sermorelin in adult endocrinology is as a stimulus in the GHRH-arginine test, retained as a diagnostic option for adult GH deficiency in current Endocrine Society and AACE guidelines, with the caveat that U.S. supply has been dependent on compounded GHRH analog availability since the Geref withdrawal [molitch2011, yuen2019].

Adult therapeutic and anti-aging evidence: Vittone 1997 [vittone1997] and Khorram 1997 [khorram1997_may, khorram1997_nov] reported small randomized studies of nightly subcutaneous sermorelin (typically 1-2 micrograms/kg) in healthy older adults over 8-16 weeks, with rises in IGF-1, increases in lean body mass on the order of 1-2 kg, and reductions in trunk fat in some analyses; Corpas 1992 [corpas1992] reported reversal of the age-related GH/IGF-1 decline with twice-daily sermorelin in older men [fda_label_geref]. Walker 2006 [walker2006] reviewed these data and the rationale for GHRH stimulation as a more physiologic alternative to recombinant GH in adult-onset GH insufficiency. None of these studies addresses morbidity or mortality endpoints, and the 2007 Liu systematic review in Annals of Internal Medicine [liu2007] concluded that growth hormone administration in healthy older adults produces small body composition changes without functional benefit and is associated with more edema, arthralgia, carpal tunnel syndrome, and glucose intolerance than placebo [neyzi1993; hummelink1993]. Sermorelin should not be framed as an anti-aging therapy on the basis of the available evidence. WADA prohibits GHRH analogs including sermorelin in competitive sport [wada_prohibited_list]. Compounded sermorelin is dispensed under 503A on patient-specific prescriptions only [fda503a].

Why Personalized Sermorelin

The historical Geref label set sermorelin at 30 micrograms per kilogram nightly for pediatric growth hormone deficiency, and the adult investigational regimens in the published literature ran 1 to 2 micrograms per kilogram at bedtime for 8 to 16 weeks. Neither schedule was calibrated to your baseline IGF-1, your age- and sex-adjusted IGF-1 target range, your sleep-onset timing (the pulse the drug is meant to amplify happens during your own slow-wave sleep), or your tolerance for injection-site reactions, flushing, and headache. Sermorelin works by nudging the patient's own pituitary, so the response curve is the patient's, not the trial cohort's.

That gap is what a 503A compounding pharmacy is built for. A prescriber working from a baseline IGF-1 and a documented indication can write a microgram dose that lands inside the age-adjusted IGF-1 target rather than a fixed milligram strength, anchor the injection to the patient's actual bedtime to preserve the overnight GH pulse pattern that pulsatile dosing depends on, titrate down a step if the first weeks bring flushing or local reactions, and, where the prescriber has documented rationale, coordinate sermorelin with related GHRH or GHRP peptides like CJC-1295 or ipamorelin instead of forcing a one-molecule fit. Follow-up IGF-1 then drives the next adjustment, not a printed dose card.

This is what pharmacy looked like before mass manufacturing arrived. A prescriber wrote the order for one patient, a pharmacist prepared it for that patient, and the label carried that patient's name. Compounded sermorelin is that older arrangement, kept honest by modern oversight.

Quick Facts About Sermorelin

Category: Synthetic growth hormone-releasing hormone (GHRH) analog, the N-terminal 1-29 amino acid fragment of human GHRH, the shortest sequence that retains full GHRH-receptor agonist activity

Active ingredient: Sermorelin acetate, GRF(1-29)-NH2, a 29-amino-acid peptide corresponding to residues 1-29 of native human growth hormone-releasing hormone

Historical FDA status: Geref (sermorelin acetate, Serono) was FDA-approved in 1990 as a diagnostic test for growth hormone deficiency and in 1997 as a therapeutic for the long-term treatment of idiopathic growth hormone deficiency in children with growth failure. The manufacturer voluntarily withdrew Geref from the U.S. market in 2008 for commercial reasons unrelated to safety or efficacy.

Current FDA status: There is no FDA-approved sermorelin product available in the United States. Sermorelin is not approved for any indication in any population.

Route: Subcutaneous injection (the Geref label specified daily bedtime subcutaneous dosing in children); intravenous and intranasal routes have been studied

Evidence posture: Pediatric growth hormone deficiency: well_studied (basis of the 1997 Geref approval [neyzi1993, chen1993, hummelink1993, grunt1995]). Adult growth hormone deficiency diagnostics (GHRH-arginine stimulation): well_studied [molitch2011, yuen2019]. Adult-onset GH insufficiency therapy, body composition, sleep, anti-aging: emerging at best [walker2006, vittone1997, khorram1997_may, khorram1997_nov, corpas1992]. Anti-aging in healthy adults: not supported by adequately powered outcomes trials [liu2007].

Compounded under: 503A, patient-specific prescription only, with documented clinical context (typically adult GH insufficiency with biochemical confirmation, or a clinical setting where GHRH-axis stimulation is the rational target)

Important honest framing: Sermorelin is not a fountain of youth. Anti-aging claims for sermorelin rest on short-term studies of IGF-1 and body composition surrogates [khorram1997_may, khorram1997_nov, vittone1997]; large-scale outcome data are absent, and the 2007 Annals of Internal Medicine systematic review of growth hormone in the healthy elderly [liu2007] documented small body composition changes with no functional benefit and increased adverse events. WADA prohibits GHRH analogs including sermorelin in competitive sport.

SPECIALS: PATIENT-SPECIFIC PRESCRIPTION ONLY

Sermorelin described in this monograph is a 503A compounded preparation. Every dose is made on a prescription, for a named patient, by a licensed pharmacist. It is not a stocked, mass-manufactured product.

- **Made to order, not off a shelf.** No batch sits in a warehouse waiting for buyers. Your prescription triggers the prep.
- **Named-patient label.** The bottle carries one patient's name. The batch records carry one prescription.
- **Dose, strength, and route chosen for the patient.** A prescriber decides what gets compounded, not a manufacturer who set the strength for a trial population.
- **Licensed pharmacist on the hook.** A real person, with a license that can be pulled, signs off on every prep. State inspectors check the facility.
- **Compounded drugs are not FDA-approved.** They should not be evaluated using branded-drug trial data alone. Availability varies by state and prescribed medication.

How This Differs from a Research-Use-Only Website

A research-use-only website ships a vial from a warehouse. There is no prescription, no pharmacist, no facility inspection, and no way to recall the product if something is wrong with it. If the vial is mislabeled, contaminated, or under-potent, there is nobody whose license is at stake.

A 503A compounding pharmacy is the other thing. The doctor writes the prescription. A licensed pharmacist, whose name is on the label, prepares the medicine in a facility the state inspects. If something goes wrong, there is a person and a license on the hook, and a documented chain of custody on every lot. That accountability is what makes it safe.

What is Sermorelin?

Sermorelin (sermorelin acetate; GRF(1-29)-NH2) is a synthetic 29-amino-acid peptide corresponding to residues 1-29 of native human growth hormone-releasing hormone (GHRH 1-44). The 1-29 sequence is the shortest fragment of native GHRH that retains full agonist activity at the pituitary GHRH receptor, identified in classical structure-activity work in the early 1980s and developed clinically as a GHRH-axis probe and therapeutic stimulus during that decade [thorner1986, grossman1986].

Sermorelin was developed by Salk Institute investigators and Serono and was approved by FDA as Geref in 1990 as a diagnostic stimulus for evaluation of growth hormone secretion, and in 1997 as an extended-use therapeutic for long-term treatment of idiopathic growth hormone deficiency in children with growth failure [prakash1999, fda_label_geref]. The product was supplied as a lyophilized powder for reconstitution and subcutaneous injection. Serono voluntarily withdrew Geref from the U.S. market in 2008 for commercial reasons unrelated to safety or efficacy. No FDA-approved sermorelin product is available in the United States today.

Sermorelin under 503A is compounded as a sterile lyophilized powder or solution for subcutaneous injection on patient-specific prescriptions written by licensed prescribers for identified patients with documented clinical context. The compounded preparation is not bioequivalent to the historical Geref product, and the published efficacy evidence for sermorelin was generated with the manufactured Geref formulation and does not transfer to compounded preparations without separate stability, potency, and tolerability evaluation.

How Sermorelin Works

Sermorelin binds and activates the GHRH receptor on the pituitary somatotrope, stimulating pulsatile endogenous release of growth hormone (GH). Because sermorelin acts on the patient's own pituitary, GH secretion preserves a physiologic pulsatile pattern, mechanistically distinct from continuous exposure produced by direct administration of recombinant human GH [thorner1986, corpas1992]. The downstream rise in serum insulin-like growth factor-1 (IGF-1) mediates many of the peripheral effects associated with chronic GHRH-receptor agonism, including modest lipolysis and lean-mass changes in adults [vittone1997, khorram1997_may, khorram1997_nov].

Sermorelin has a short plasma half-life of minutes after subcutaneous administration, characteristic of small peptide GHRH analogs. Despite this short pharmacokinetic exposure, the discrete pulsatile GH response generated per dose is sufficient to support nightly subcutaneous dosing regimens in research protocols and in the historical pediatric labeled regimen [grunt1995, vittone1997]. The mechanism is dependent on intact pituitary somatotrope function, patients with hypopituitarism, prior pituitary surgery,

or head irradiation may have insufficient endogenous GH reserves to mount a clinically meaningful response.

Sermorelin's GHRH-receptor agonism is shared by other GHRH-axis peptides used clinically and in research, most notably tesamorelin (a stabilized GHRH (1-44) analog with FDA approval for HIV-associated lipodystrophy), CJC-1295 (a longer-acting GHRH (1-29) analog), and other 1-29 analogs developed in academic and industrial programs. Sermorelin is functionally and mechanistically distinct from ghrelin receptor agonists (ipamorelin, GHRP-2, GHRP-6, hexarelin), which act at a different pituitary receptor.

Biological Role of Sermorelin

Growth hormone-releasing hormone is the master positive regulator of the somatotrope axis. Hypothalamic GHRH neurons secrete GHRH into hypophyseal portal blood in a pulsatile pattern that drives pulsatile pituitary GH release, which in turn stimulates hepatic and tissue IGF-1 production. The axis mediates linear growth in childhood, body composition regulation across the lifespan (lean mass, visceral adiposity, insulin sensitivity), and tissue-specific effects on bone, skeletal muscle, and immune function. Native GHRH is opposed in real time by somatostatin from a separate hypothalamic neuronal population, and the balance of GHRH-versus-somatostatin tone determines GH pulse amplitude and frequency.

With aging, integrated 24-hour GH secretion declines markedly, by approximately 50% from young adulthood to age 60-70, accompanied by parallel declines in serum IGF-1. This 'somatopause' was the rationale for early sermorelin trials in older adults [corpas1992, vittone1997]. Whether the age-related decline represents a deficiency state warranting pharmacologic intervention or a physiologic adaptation is debated, and the 2007 Liu systematic review [liu2007] of GH administration in healthy older adults concluded that the body composition signal is small and the functional benefit unproven.

Detailed Mechanism of Sermorelin

Native human GHRH is a 44-amino-acid hypothalamic peptide secreted into hypophyseal portal blood and is the principal positive regulator of pituitary GH release. Structure-activity work in the early 1980s by Vale, Rivier, and colleagues at the Salk Institute identified the 1-29 N-terminal fragment as the shortest sequence retaining full agonist activity at the pituitary GHRH receptor, sermorelin (GRF(1-29)-NH2) was developed directly from this finding. The 1-29 sequence is rapidly cleaved at the Tyr-Ala N-terminus by plasma dipeptidyl peptidase-IV (DPP-IV), accounting for the short minute-scale plasma half-life [thorner1986, grossman1986].

Mechanistic pharmacology in humans is well characterized. Thorner and colleagues (Vance, Evans, Thorner, 1986) [thorner1986] reported dose-response relationships of GHRH(1-29)-NH2 (the norleucine-substituted analog used in early sermorelin development) administered by intravenous, subcutaneous, and

intranasal routes in healthy men, establishing the subcutaneous and intravenous routes as the clinically meaningful pathways for acute GH stimulation. Subsequent work in healthy older adults established that nightly subcutaneous sermorelin restores pulsatile GH secretion patterns closer to younger-adult norms, with elevations in IGF-1 to mid-normal-young-adult range over weeks of dosing. Friend and colleagues 1997 [friend1997] characterized the GH burst architecture under cholinergic modulation, providing context for how somatostatinergic tone modulates the GH response to GHRH stimulation.

In pediatric growth hormone deficiency, the rationale for sermorelin is restoration of the patient's own pituitary pulse architecture [corpas1992; neyzi1993; chen1993]. Comparative pediatric studies of GHRH (1-29) versus recombinant GH demonstrated growth velocity gains in idiopathic GHD with intact pituitary somatotrope function, supporting the 1997 Geref label for long-term treatment of pediatric idiopathic GHD [khorram1997_nov; grunt1995; hernandez1988]. Tauber and colleagues 1989 [tauber1989] reported modification of 24-hour GH secretion with continuous subcutaneous GHRH infusion. Hümmelink and colleagues 1993 [hummelink1993] demonstrated intranasal sermorelin activity in children with GH neurosecretory dysfunction.

Diagnostically, GHRH (1-29), administered as sermorelin or in combination with arginine, remains a stimulus in the GHRH-arginine test for evaluation of adult GH deficiency, retained as a guideline-recommended diagnostic option by the 2011 Endocrine Society [molitch2011] and 2019 AACE [yuen2019] adult GHD guidelines. Use of the GHRH-arginine test in adults with hypothalamic pathology can yield false-negative results because the test bypasses upstream hypothalamic regulation [molitch2011]. Grugni and colleagues 2006 [grugni2006] characterized GHRH+arginine response patterns in adult Prader-Willi syndrome, an inherited disorder with somatotrope-axis dysfunction.

Pharmacokinetically, sermorelin is cleared by proteolytic catabolism with no cytochrome P450 involvement; renal and hepatic dosing adjustments are not specified in the historical Geref labeling. Pharmacodynamically, with chronic nightly subcutaneous dosing in adults, IGF-1 rises to a new steady state within approximately 2-4 weeks and declines back toward baseline within weeks of discontinuation, parallel to other GHRH analogs [vittone1997, khorram1997_may].

Sermorelin Research History

GHRH was isolated and sequenced in 1982 from human pancreatic islet-cell tumors causing acromegaly, in parallel work by Guillemin and Vale. Structure-activity studies through 1983-1985 established that the N-terminal 1-29 fragment retains full GHRH-receptor agonist activity, with the 1-44 sequence being the native form and 1-40 and 1-29 forms also retained physiologic activity. Sermorelin (GRF(1-29)-NH2) was developed by Salk Institute and Serono on the basis of this work and entered human clinical investigation in the mid-1980s [thorner1986, grossman1986].

Acute human dose-response and route-of-administration studies by Vance, Evans, Thorner, and colleagues (1986, Clin Pharmacol Ther) [thorner1986] established the IV, SC, and intranasal routes and characterized

GH secretory responses to a Norleucine-27-substituted sermorelin analog in healthy men. Pediatric studies through the late 1980s and 1990s established growth velocity gains with daily or twice-daily subcutaneous GHRH (1-29) in children with idiopathic growth hormone deficiency, with response rates and magnitude of growth comparable to recombinant GH in selected responders and inferior in patients with structural pituitary lesions [hernandez1988; tauber1989; neyzi1993]. FDA approved Geref (sermorelin acetate, Serono) in 1990 as a diagnostic stimulus for GH-axis evaluation, and approved an extended-use Geref formulation in 1997 for long-term treatment of idiopathic GH deficiency in children with growth failure [fda_label_geref, prakash1999] [chen1993].

Adult-aging studies in the 1990s evaluated sermorelin as a tool to reverse the age-related GH/IGF-1 decline. Corpas and colleagues (1992, JCEM) [corpas1992] reported that twice-daily subcutaneous GHRH (1-29) in older men over weeks raised mean overnight GH and serum IGF-1 toward mid-normal-young-adult range. Vittone and colleagues (1997, Metabolism) [vittone1997] reported single nightly subcutaneous injections of sermorelin in healthy older adults over 16 weeks raised mean overnight GH and IGF-1 with modest reductions in body fat. Khorram and colleagues (1997, JCEM May and Nov) [khorram1997_may; khorram1997_nov] reported endocrine and metabolic effects of long-term (16-week) administration of sermorelin in healthy older adults with increases in lean body mass on the order of 1-2 kg and reductions in trunk fat. Friend and colleagues 1997 [friend1997] characterized somatostatinergic modulation of GH burst architecture.

Serono voluntarily withdrew Geref from the U.S. market in 2008 for commercial reasons unrelated to safety or efficacy. The FDA discontinuation removed the only U.S.-approved sermorelin product, but the GHRH-arginine test using sermorelin or a comparable GHRH analog remained a guideline-recommended diagnostic option for adult GH deficiency in subsequent Endocrine Society (2011) [molitch2011] and AACE (2019) [yuen2019] adult GHD guidelines, generally supplied through compounding or research-grade material since 2008. Walker 2006 (Clinical Interventions in Aging) [walker2006] reviewed the rationale for GHRH stimulation as an alternative to recombinant GH in adult-onset GH insufficiency. The 2007 Liu systematic review (Annals of Internal Medicine) [liu2007] of growth hormone administration in healthy older adults, which informs the GHRH-stimulation literature by analogy, concluded that body composition changes are small and functional benefit unproven, with increased rates of edema, arthralgia, carpal tunnel syndrome, and glucose intolerance [hummelink1993; grunt1995]. The 1990 Rudman NEJM trial of recombinant GH in older men [rudman1990] is frequently invoked in popular anti-aging coverage but did not measure functional outcomes and used recombinant GH rather than sermorelin. Grugni and colleagues 2006 [grugni2006] reported GHRH+arginine response patterns in adult Prader-Willi syndrome. WADA includes GHRH analogs (sermorelin, tesamorelin, CJC-1295) on its prohibited list for competitive sport [wada_prohibited_list].

Sermorelin Timeline

1982 • GHRH isolated and sequenced from human pancreatic tumors causing acromegaly (Guillemin and Vale, parallel work)

1986 • Vance, Evans, Thorner et al [thorner1986]. (Clin Pharmacol Ther) characterize IV, SC, and intranasal dose-response of GHRH(1-29)-NH2 in healthy men

1986 • Grossman (Clin Endocrinol Metab) reviews GHRH structure-activity and clinical pharmacology [grossman1986]

1988 • Hernández et al [hernandez1988]. (Horm Res) report subcutaneous GHRH for short stature in children

1989 • Tauber et al [tauber1989]. (Acta Paediatr Scand Suppl), continuous subcutaneous GHRH infusion modifies 24-hour GH secretion

1990 • FDA approves Geref (sermorelin acetate, Serono) as a diagnostic stimulus for evaluation of growth hormone secretion [fda_label_geref]

1990 • Rudman et al [rudman1990]. (NEJM) report effects of recombinant human growth hormone in men over 60, the trial later widely invoked in anti-aging coverage, using recombinant GH rather than sermorelin

1992 • Corpas et al [corpas1992]. (JCEM), twice-daily subcutaneous GHRH (1-29) reverses age-related GH/IGF-1 decline in older men

1993 • Chen et al., Hümmelink et al., Neyzi et al [chen1993; hummelink1993; neyzi1993]. (Acta Paediatr Suppl), comparative pediatric studies of GHRH (1-29) vs recombinant GH in idiopathic GHD

1995 • Grunt et al [grunt1995]. (Acta Paediatr), long-term GHRH (1-29) in significantly short children, growth velocity gains over multi-year follow-up

1997 • FDA approves extended-use Geref formulation for long-term treatment of idiopathic growth hormone deficiency in children with growth failure [fda_label_geref; prakash1999]

1997 • Vittone et al [vittone1997]. (Metabolism), Khorram et al [khorram1997_may; khorram1997_nov]. (JCEM May and Nov), 16-week nightly sermorelin in healthy older adults raises IGF-1 and produces modest body composition changes

1997 • Friend et al [friend1997]. (Eur J Endocrinol), somatostatinergic modulation of GH burst architecture under pyridostigmine, informing GHRH-stimulation physiology

1999 • Prakash & Goa (BioDrugs) review sermorelin use in diagnosis and treatment of children with idiopathic GHD [prakash1999]

2006 • Walker (Clin Interv Aging) reviews sermorelin as an alternative approach to adult-onset growth hormone insufficiency management [walker2006]

2006 • Grugni et al [grugni2006]. (Clin Endocrinol Oxf), GHRH+arginine response patterns in adult Prader-Willi syndrome

2007 • Liu et al [liu2007]. (Ann Intern Med), systematic review of growth hormone in healthy elderly: small body composition changes without functional benefit, increased adverse events

2008 • Serono voluntarily withdraws Geref from the U.S. market for commercial reasons unrelated to safety or efficacy; no FDA-approved sermorelin product available in the U.S [fda_label_geref]. since

2011 • Endocrine Society adult GH deficiency clinical practice guideline (Molitch et al., JCEM) retains GHRH-arginine test as a guideline-recommended diagnostic option [molitch2011]

2019 • AACE/ACE adult GH deficiency clinical practice guideline (Yuen et al., Endocr Pract) retains GHRH-arginine test as a guideline-recommended diagnostic option [yuen2019]

Clinical Contexts for Sermorelin

Idiopathic growth hormone deficiency in children (historical Geref indication)

WELL STUDIED

Historical FDA-approved indication (1997 Geref label). The manufactured product was withdrawn in 2008. No FDA-approved sermorelin product is currently available in the United States, and contemporary pediatric GHD is treated with recombinant growth hormone.

The historical Geref pediatric indication was supported by controlled and open-label studies of subcutaneous GHRH (1-29) in children with idiopathic GHD and intact pituitary somatotrope function, demonstrating growth velocity gains [hernandez1988; tauber1989; hummelink1993]. Response was generally inferior in patients with structural pituitary lesions or hypothalamic damage, reflecting the requirement for intact pituitary GHRH-receptor signaling. The 1997 Geref approval was withdrawn commercially in 2008 [prakash1999; fda_label_geref]. RonanRx does not compound sermorelin for pediatric use; pediatric GHD is treated with recombinant growth hormone per current pediatric endocrinology guidelines [neyzi1993; chen1993; grunt1995].

GHRH-arginine diagnostic stimulation test for adult GH deficiency WELL STUDIED

Guideline-recommended diagnostic use. Not a therapeutic indication. Conducted under endocrinology supervision with formal testing protocols.

GHRH (1-29) administered with intravenous arginine remains a guideline-recommended diagnostic stimulus for adult GH deficiency in the 2011 Endocrine Society [molitch2011] and 2019 AACE [yuen2019] adult GHD guidelines. Test sensitivity is high in adult-onset hypopituitarism but lower in patients with hypothalamic-level pathology, where the test bypasses upstream regulation and may yield false-negative results [molitch2011]. Following the 2008 Geref withdrawal, GHRH analog supply for this test has been dependent on compounding or research-grade material. Grugni and colleagues 2006 [grugni2006] characterized GHRH+arginine response in adult Prader-Willi syndrome.

Adult growth hormone insufficiency, therapeutic GHRH stimulation EMERGING

Investigational. No adequately powered outcomes trial. Compounded sermorelin under 503A is appropriate only with documented adult GH-axis insufficiency, biochemical confirmation, prescriber-documented rationale for GHRH stimulation rather than recombinant GH replacement, and monitoring.

Walker 2006 [walker2006] reviewed the rationale for GHRH-axis stimulation as a more physiologic alternative to recombinant GH replacement in adult-onset GH insufficiency with intact pituitary somatotrope function. Short-term studies in older adults documented IGF-1 elevation and modest body composition changes, but no controlled trial has demonstrated improvements in morbidity, mortality, or function. The published evidence does not support routine substitution of sermorelin for recombinant GH in adult GHD [khorram1997_nov]. RonanRx compounds sermorelin in this context only on a patient-specific prescription with documented clinical rationale and monitoring plan [corpas1992; vittone1997; khorram1997_may].

Off-Label Uses of Sermorelin

Anti-aging and body composition in healthy adults EMERGING

Not an FDA-approved indication. Evidence for sermorelin as an anti-aging therapy is weak. RonanRx does not compound sermorelin for anti-aging indications.

Short-term studies of nightly sermorelin in healthy older adults documented IGF-1 elevation and small body composition changes (1-2 kg lean mass, modest trunk fat reduction) over 8-16 weeks. None of these studies measured functional or morbidity endpoints. The 2007 Liu systematic review of growth hormone in healthy older adults [liu2007], informative by analogy, concluded that body composition changes are small, functional benefit is unproven, and rates of edema, arthralgia, carpal tunnel syndrome, and glucose intolerance are higher than placebo [vittone1997; khorram1997_may]. The Rudman 1990 NEJM trial [rudman1990] commonly cited in popular anti-aging coverage used recombinant GH, not sermorelin, and did not measure functional outcomes. Sermorelin should not be framed as an anti-aging therapy on the basis of the available evidence [khorram1997_nov; corpas1992].

Athletic performance and ergogenic use EMERGING

Not an FDA-approved indication. WADA prohibits GHRH analogs including sermorelin in competitive sport.

WADA includes growth hormone-releasing factors and GHRH analogs (sermorelin, tesamorelin, CJC-1295, CJC-1293) on the prohibited list under S2 (Peptide Hormones, Growth Factors, Related Substances and Mimetics) for in- and out-of-competition use [wada_prohibited_list]. No clinical evidence supports sermorelin as a safe or effective ergogenic agent in athletes. RonanRx does not compound sermorelin for athletic performance, body composition in adults without documented GH insufficiency, or other ergogenic indications.

Sleep quality, recovery, general well-being EMERGING

Not an FDA-approved indication. Not supported by adequately powered evidence. RonanRx does not compound sermorelin for these indications without documented clinical context.

Consumer marketing of sermorelin frequently includes claims of improved deep sleep, accelerated recovery, and general well-being. The published evidence is limited to changes in overnight GH secretion patterns and surrogate measures in short studies [vittone1997, khorram1997_may, khorram1997_nov]; no controlled trial has demonstrated improvements in patient-reported sleep quality, recovery, or well-being endpoints. These uses sit outside any documented clinical indication.

FDA-Approved Uses of Sermorelin

Geref (sermorelin acetate, Serono) was FDA-approved in 1990 as a diagnostic stimulus for evaluation of growth hormone secretion [fda_label_geref]. An extended-use Geref formulation was FDA-approved in 1997 for long-term treatment of idiopathic growth hormone deficiency in children with growth failure [prakash1999]. Serono voluntarily withdrew Geref from the U.S. market in 2008 for commercial reasons unrelated to safety or efficacy. There is no FDA-approved sermorelin product available in the United States today, and sermorelin is not approved for any indication, in any population, in current FDA labeling. Compounded sermorelin under 503A is not FDA-approved.

Compounded Sermorelin (503A)

Sermorelin is not currently FDA-approved for any indication in the United States. Compounded sermorelin under 503A is dispensed on patient-specific prescriptions written by licensed prescribers for identified patients with documented clinical context. Because there is no manufactured FDA-approved sermorelin product on the U.S. market, FDA's essentially-a-copy-of-an-approved-drug guidance [fda_essentially_a_copy] does not directly constrain compounded sermorelin in the way it constrains compounded copies of currently marketed products (such as tesamorelin/Egrifta or semaglutide/Ozempic) [fda_label_geref]. Compounding pharmacies dispensing sermorelin nonetheless operate under the patient-specific 503A framework with full pharmacist review [corpas1992; neyzi1993; chen1993].

RonanRx compounds sermorelin only on a patient-specific prescription with documented clinical context, typically (1) adult growth hormone insufficiency with biochemical confirmation and prescriber-documented rationale for GHRH-axis stimulation rather than recombinant GH replacement, or (2) other prescriber-documented clinical settings where GHRH-receptor agonism is the rational therapeutic target [fda_label_geref] [vittone1997; khorram1997_may]. RonanRx does not compound sermorelin for anti-aging, athletic performance, body composition in adults without documented GH insufficiency, sleep optimization, or other off-label consumer indications. These uses sit outside any documented clinical indication and outside the published efficacy program for sermorelin [grunt1995; prakash1999].

Compounded sermorelin preparations are typically dispensed as sterile lyophilized powder for reconstitution and subcutaneous injection prior to administration [fda503a]. The compounded preparation is not bioequivalent to the historical Geref product; PK/PD characteristics may differ from the manufactured product depending on excipient profile, lyophilization conditions, and container closure. The published pediatric efficacy evidence for Geref was generated with the manufactured product and does not transfer to compounded preparations without separate stability, potency, and tolerability evaluation [fda_label_geref]. Adult-aging studies used research-grade GHRH (1-29) preparations [khorram1997_nov].

Sermorelin Formulations and Routes

Form	Concentration	Description
Sterile lyophilized powder for subcutaneous injection (compounded)	Custom, typically reconstituted to deliver microgram-to-milligram per dose on a patient-specific prescription; pediatric historical Geref dosing was 30 micrograms/kg subcutaneously once daily at bedtime	Sterile lyophilized preparation compounded under USP General Chapter <797> on a patient-specific prescription. Container closure, excipient profile, and lyophilization conditions are documented per batch. Beyond-use dating follows USP <797> requirements and pharmacy stability data.

Routes used in published literature: subcutaneous, intravenous, intranasal.

Sermorelin Dosing

Route	Population	Range	Duration	Study type
Subcutaneous	Children with idiopathic growth hormone deficiency (historical Geref labeled regimen, withdrawn 2008)	30 micrograms/kg subcutaneously once daily at bedtime per the historical Geref label for long-term treatment of idiopathic GHD	Continued through growth period in pediatric GHD per historical labeling	Historical FDA-approved labeled regimen (Geref, withdrawn 2008)
Subcutaneous	Healthy older adults (investigational, anti-aging surrogate-endpoint studies)	1-2 micrograms/kg subcutaneously at bedtime as used in Vittone 1997 and Khorram 1997 studies, or 1 mg subcutaneously twice daily as used in Corpas 1992	8-16 weeks in published trials	Randomized investigational dosing in healthy older adults
Intravenous	Adults undergoing GHRH-arginine stimulation testing for adult GH deficiency diagnosis	1 microgram/kg IV bolus GHRH with 0.5 g/kg IV arginine infusion over 30 minutes, with serial GH sampling per standard protocol	Single test (acute)	Guideline-recommended diagnostic test

Doctor-prescribed only. The historical pediatric Geref regimen was 30 micrograms/kg subcutaneously once daily at bedtime; the manufactured product was withdrawn in 2008 and RonanRx does not compound

sermorelin for pediatric use [fda_label_geref] [corpas1992]. Adult investigational regimens have used nightly subcutaneous sermorelin in the range of 1-2 micrograms/kg, or twice-daily dosing of 1 mg, in research protocols of 8-16 weeks duration [vittone1997]. No FDA-approved adult therapeutic regimen exists.

Patient-specific compounded prescriptions should include the indication, prescribed dose and frequency, duration of therapy with reassessment intervals, baseline and follow-up IGF-1 monitoring plan, baseline and follow-up glycemic monitoring (given the GH-axis glucose-tolerance signal), and contraindication screening (hypothalamic-pituitary axis disruption, active malignancy, pituitary tumor). RonanRx does not fill sermorelin prescriptions without documented clinical context [fda_label_geref] [khorram1997_may; khorram1997_nov].

Sermorelin Safety

Sermorelin safety in the controlled trial literature is characterized primarily by injection-site reactions (erythema, pain, swelling, pruritus at the injection site), flushing, headache, transient mild glucose intolerance, and an expected dose-dependent rise in IGF-1. Injection-site reactions were typically mild, self-limited, and infrequently caused discontinuation across the pediatric and adult-aging trial literature [21]. Hypersensitivity reactions including urticaria, rash, and rare anaphylaxis have been reported with peptide GHRH analogs as a class.

The IGF-1 elevation is a class-relevant consideration. Sermorelin produces a sustained rise in serum IGF-1 reflecting endogenous GH secretion; long-term IGF-1 elevation has theoretical concerns regarding effects on neoplasia, although no controlled trial of sermorelin has been large enough or long enough to characterize neoplasia risk [10]. Glucose intolerance is a class signal: small increases in fasting plasma glucose and modest reductions in insulin sensitivity were observed in some adult-aging studies [12][13], paralleling the broader GH-axis literature [18]. Sermorelin should not be used in patients with active malignancy, and known or suspected pituitary tumor or other CNS tumor is a contraindication consistent with the historical Geref label [21].

Long-term cardiovascular safety has not been established for sermorelin in any population. The pediatric labeled population was treated for growth velocity gains, not cardiovascular outcomes. The adult-aging trial literature is short-duration and surrogate-endpoint. The 2007 Liu systematic review of growth hormone in healthy older adults [18] documented increased rates of edema, arthralgia, carpal tunnel syndrome, and glucose intolerance with GH administration; whether GHRH-stimulation-based regimens carry an equivalent profile has not been characterized in equivalently powered studies [111]. WADA prohibits GHRH analogs including sermorelin in competitive sport [26] [21].

Contraindications

Sermorelin is contraindicated in patients with hypersensitivity to sermorelin or to any excipient in the compounded preparation. Consistent with the historical Geref label and the GHRH-analog class, sermorelin is contraindicated in patients with active malignancy (either newly diagnosed or recurrent), in patients with known or suspected pituitary tumor or other CNS tumor, and in pregnancy. Severe disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism with structural pituitary lesion, head irradiation, or head trauma may render the pituitary unable to mount a meaningful GH response to GHRH stimulation; sermorelin is not appropriate in these populations as a therapeutic [21].

Caution applies in patients with diabetes mellitus, glucose intolerance, or risk factors for diabetes given the labeled glucose intolerance signal across the GH-axis class. Concomitant glucocorticoid therapy may blunt the GH response to GHRH. Sermorelin should be discontinued in patients who develop signs or symptoms of pituitary or other neoplasia during therapy [18].

Drug interactions

Sermorelin is a peptide cleared by proteolytic catabolism and is not metabolized by cytochrome P450 enzymes; clinically significant CYP-mediated drug-drug interactions are not expected [21]. Glucocorticoid replacement requirements may need adjustment in patients receiving concomitant glucocorticoids, which suppress the GH response to GHRH. The labeled glucose intolerance signal warrants attention in patients receiving insulin or oral hypoglycemic agents, where small changes in glycemic control may require dose adjustment of antidiabetic therapy.

Concomitant thyroid hormone, sex steroid, or somatostatin analog therapy can modulate the GH response to GHRH stimulation. Pyridostigmine and other cholinergic agents amplify GH burst mass by reducing somatostatinergic tone [14] and can confound interpretation of GH responses to sermorelin if administered concurrently [21]. Concomitant ghrelin receptor agonists (ipamorelin, GHRP-2, GHRP-6, hexarelin) produce additive GH-secretion effects; no controlled trial supports combining these classes therapeutically.

Adverse events

Across the historical pediatric trial program and adult-aging research literature, the most common adverse events with sermorelin versus placebo were injection-site reactions (erythema, pain, swelling, pruritus at site), flushing, transient headache, occasional dysgeusia or nausea, and expected dose-dependent rises in IGF-1 [15]. Injection-site reactions were typically mild to moderate, concentrated in the early weeks of therapy, and infrequently caused discontinuation. Hypersensitivity reactions occurring as systemic urticaria, pruritus, flushing, and rare anaphylaxis have been reported across the peptide GHRH-analog class [1112133].

Anti-sermorelin antibodies were detected in a minority of patients across the pediatric Geref experience; antibody formation did not consistently predict loss of efficacy. Small increases in fasting plasma glucose, fasting insulin, and modest reductions in insulin sensitivity were observed in some adult-aging studies; rare

progression to overt diabetes was not characterized. The GH-axis adverse event profile documented by Liu and colleagues 2007 [18] in healthy older adults on recombinant GH, edema, arthralgia, carpal tunnel syndrome, glucose intolerance, is plausibly relevant to chronic GHRH-stimulation regimens by analogy, though direct controlled trial data of equivalent power are not available [110].

Monitoring Sermorelin Therapy

Baseline assessment should include a focused history for hypothalamic-pituitary axis disruption, current or prior malignancy, pituitary tumor or sellar mass, diabetes mellitus or glucose intolerance, pregnancy status, and hypersensitivity [fda_label_geref]. Baseline laboratory should include IGF-1 (interpreted against age- and sex-adjusted normal range), fasting plasma glucose and HbA1c, and routine metabolic panel. Where adult GH deficiency is the indication, biochemical confirmation by stimulation testing per current guidelines [molitch2011, yuen2019] should be documented prior to therapy.

On therapy: IGF-1 at baseline and periodically (typically 4-8 weeks after initiation and at clinically appropriate intervals thereafter) with dose adjustment if IGF-1 exceeds two standard deviations above the age- and sex-adjusted normal range; fasting plasma glucose and HbA1c at intervals appropriate to the patient's risk; assessment of injection-site tolerance at clinic visits; reassessment of indication-specific response (growth velocity in pediatric historical use; body composition or symptom score in adult contexts) at appropriate intervals [fda_label_geref]. Patients should be educated to recognize and report symptoms of hypersensitivity, hyperglycemia, edema, arthralgia, carpal tunnel symptoms, and any new neurologic or visual symptoms that might suggest pituitary pathology.

Sermorelin in Special Populations

Sermorelin Evidence Quality

Evidence supporting the historical Geref pediatric indication for idiopathic growth hormone deficiency is well-studied but dated [chen1993; hummelink1993; prakash1999]. Controlled and open-label studies through the 1980s and 1990s demonstrated growth velocity gains with subcutaneous GHRH (1-29) in children with intact pituitary somatotrope function, supporting the 1997 FDA approval [tauber1989; khorram1997_nov; corpas1992]. Geref was voluntarily withdrawn in 2008 for commercial reasons. Contemporary pediatric GHD is treated with recombinant growth hormone [hernandez1988; vittone1997; khorram1997_may].

Evidence for sermorelin as a diagnostic GHRH-arginine stimulus in adult GH deficiency is well-studied, with retained guideline-recommended status in both the 2011 Endocrine Society [molitch2011] and 2019

AACE [yuen2019] adult GHD clinical practice guidelines, modulated by the recognition that hypothalamic pathology can yield false-negative tests [molitch2011].

Evidence for adult therapeutic use of sermorelin is emerging and surrogate-endpoint. Short randomized studies in healthy older adults documented IGF-1 elevation and modest body composition changes over 8-16 weeks. Walker 2006 [walker2006] reviewed the rationale for adult-onset GH insufficiency therapy. None of this evidence base establishes morbidity, mortality, or functional benefit. The 2007 Liu systematic review of recombinant growth hormone in healthy older adults [liu2007], relevant by analogy, concluded that body composition changes are small, functional benefit is unproven, and adverse events are increased [neyzi1993; grunt1995]. Evidence for sermorelin specifically as an anti-aging therapy is weak. Sermorelin should be framed honestly: a legitimate compounded GHRH analog with a well-characterized mechanism, a defined diagnostic role, a historical pediatric indication, and limited evidence supporting routine adult therapeutic use absent documented GH-axis insufficiency.

Major Sermorelin Clinical Studies

Study	Design	Participants	Duration	Finding
Vance, Evans, Thorner et al. (1986, Clin Pharmacol Ther), Dose-response IV/SC/intranasal sermorelin in healthy men	Dose-response study of GHRH(1-29)-NH2 administered intravenously, subcutaneously, and intranasally in healthy men	—	—	Established the IV, SC, and intranasal dose-response relationships and route comparability of sermorelin in healthy men; foundational human pharmacology [thorner1986]
Corpas et al. (1992, JCEM), Twice-daily GHRH (1-29) reverses age-related GH/IGF-1 decline in old men	Randomized controlled study of twice-daily subcutaneous GHRH (1-29) in older men over weeks	—	2 weeks	Twice-daily subcutaneous sermorelin raised mean overnight GH secretion and serum IGF-1 toward mid-normal-young-adult range, reversing the age-related decline in this short-term protocol [corpas1992]
Vittone et al. (1997, Metabolism), 16-week nightly sermorelin in healthy older adults	Randomized study of single nightly subcutaneous sermorelin injections in healthy older adults	—	16 weeks	Nightly subcutaneous sermorelin raised mean overnight GH concentrations and IGF-1 over 16 weeks with modest body composition changes in healthy older adults [vittone1997]
		—	16 weeks	

Study	Design	Participants	Duration	Finding
Khorram et al. (1997, JCEM May), Long-term sermorelin endocrine and metabolic effects	Randomized study of long-term GHRH(1-29) administration in healthy older adults			Chronic nightly subcutaneous sermorelin in healthy older adults raised IGF-1 and produced modest lean-mass increases on the order of 1-2 kg with reductions in trunk fat [khorram1997_may]
Khorram et al. (1997, JCEM Nov), GHRH (1-29) administration in healthy older men and women	Randomized study of GHRH(1-29)-NH2 administration in healthy older men and women	—	16 weeks	Confirmed Khorram May 1997 findings of IGF-1 elevation and modest body composition changes in healthy older adults of both sexes, with attention to sex-specific response patterns [khorram1997_nov]
Neyzi et al. (1993, Acta Paediatr Suppl), GHRH (1-29) vs growth hormone in children	Comparative study of GHRH (1-29) versus recombinant growth hormone for stimulation of growth in children with GHD	—	—	Growth velocity gains with GHRH (1-29) comparable to recombinant GH in selected pediatric responders with intact pituitary function [neyzi1993]
Chen et al. (1993, Acta Paediatr Suppl), Comparative GH vs GHRH (1-29) in children	Comparative pediatric study of GH and GHRH (1-29)-NH2 for stimulation of growth	—	—	Documented growth velocity gains with GHRH (1-29) supporting pediatric idiopathic GHD development [chen1993]
Hümmelink et al. (1993, Acta Paediatr Suppl), Intranasal GHRH (1-29) in children with GHD	Pediatric study of intranasal GHRH (1-29)-NH2 administration in children with growth hormone neurosecretory dysfunction	—	—	Intranasal sermorelin produced GH responses sufficient to drive growth in selected pediatric responders [hummelink1993]
Grunt et al. (1995, Acta Paediatr), Long-term GHRH (1-29) in significantly short children	Long-term open-label study of GHRH (1-29) in significantly short children	—	—	Sustained growth velocity gains with long-term GHRH (1-29) in selected pediatric responders, contributing to the evidence base for the 1997 Geref pediatric indication [grunt1995]

Study	Design	Participants	Duration	Finding
Walker (2006, Clin Interv Aging), Sermorelin review for adult-onset GH insufficiency	Narrative review of sermorelin pharmacology and rationale for adult-onset growth hormone insufficiency management	—	—	Reviewed the rationale for GHRH-axis stimulation as a more physiologic alternative to recombinant GH in adults with intact pituitary somatotrope function; did not establish efficacy with morbidity endpoints [walker2006]
Liu et al. (2007, Ann Intern Med), Systematic review of GH in healthy elderly	Systematic review of randomized controlled trials of growth hormone administration in healthy older adults	—	—	Across 31 trials, GH administration in healthy older adults produced small body composition changes (lean mass +2.1 kg, fat mass -2.1 kg) without functional benefit and with increased rates of edema, arthralgia, carpal tunnel syndrome, and glucose intolerance; informative by analogy for chronic GHRH-stimulation regimens [liu2007]
Molitch et al. (2011, JCEM), Endocrine Society adult GHD guideline	Clinical practice guideline for evaluation and treatment of adult GH deficiency	—	—	Retained the GHRH-arginine test as a guideline-recommended diagnostic option for adult GH deficiency with caveats about hypothalamic-level pathology [molitch2011]
Yuen et al. (2019, Endocr Pract), AACE/ACE adult GHD guideline	AACE/ACE clinical practice guideline for management of GH deficiency in adults and patients transitioning from pediatric to adult care	—	—	Retained the GHRH-arginine test as a guideline-recommended diagnostic option and updated diagnostic and therapeutic recommendations for adult GH deficiency [yuen2019]

Sermorelin Pharmacokinetics & Pharmacodynamics

Pharmacokinetics

Sermorelin is a 29-amino-acid GHRH (1-29) peptide cleared by proteolytic catabolism. The plasma half-life after subcutaneous administration is short, typically minutes, reflecting rapid degradation by dipeptidyl

peptidase-IV (DPP-IV) cleavage at the N-terminal Tyr-Ala dipeptide. Despite the short plasma half-life, the pharmacodynamic GH response is durable enough to support nightly dosing in the historical Geref pediatric regimen and in adult-aging research protocols [thorner1986, vittone1997, khorram1997_may] [fda_label_geref].

Subcutaneous bioavailability is high enough to produce robust GH responses; intravenous and intranasal routes have also been characterized [thorner1986]. Cytochrome P450 enzymes are not implicated in clearance, and dose adjustment on the basis of renal or hepatic function was not specified in the historical Geref labeling. Compounded sermorelin preparations may differ from the historical Geref product in lyophilization conditions, excipient profile, and container closure; PK characteristics published for the manufactured product should not be assumed to translate without local stability and potency data [fda_label_geref].

Pharmacodynamics

Pharmacodynamic effects include stimulation of pulsatile endogenous GH secretion at the pituitary somatotrope, a downstream rise in serum IGF-1, and tissue effects mediated through the GH-IGF-1 axis. With chronic nightly subcutaneous dosing in healthy older adults, IGF-1 rises to a new steady state within approximately 2-4 weeks and declines back toward baseline within weeks of discontinuation [vittone1997]. Body composition changes (modest increases in lean mass, modest reductions in trunk fat) accrue over weeks to months in adults [khorram1997_may; khorram1997_nov; corpas1992].

In children with idiopathic growth hormone deficiency and intact pituitary somatotrope function, the pharmacodynamic response over months to years was growth velocity gain comparable to recombinant GH in selected responders [grunt1995, neyzi1993, chen1993]. Acutely, IV or subcutaneous sermorelin produces a discrete GH secretory pulse that is the basis for the GHRH-arginine diagnostic test in adult GH deficiency [molitch2011, yuen2019].

↓↑ Comparing Sermorelin Formulations

Sermorelin is the GHRH (1-29) N-terminal fragment with a short minute-scale plasma half-life. Tesamorelin (Egrifta, Egrifta SV, Egrifta WR, FDA-approved for HIV-associated lipodystrophy) is the GHRH (1-44) full-length analog with an N-terminal trans-3-hexenoyl modification that confers DPP-IV resistance and extends plasma half-life to roughly 26-38 minutes, supporting daily and (in the Egrifta WR depot formulation) once-weekly dosing. CJC-1295 is a GHRH (1-29) analog with substitutions and (in the DAC variant) albumin-binding chemistry that extends half-life to days; CJC-1295 is not FDA-approved and is not a commercial pharmaceutical [fda_label_geref].

Compounded sterile lyophilized sermorelin preparations vary in excipient profile, lyophilization conditions, and container closure across pharmacies. They are not bioequivalent to the historical Geref product or to any other GHRH analog [thorner1986]. Clinicians should anticipate that local PK and tolerability may

differ from the published Geref and adult-aging trial data, and re-evaluate IGF-1 response and tolerability when switching.

Sermorelin Storage and Handling

Compounded sterile injectable sermorelin is stored per the pharmacy's stability data and beyond-use date assignment under USP General Chapter <797> [usp_797]. Refrigerated storage of reconstituted product is typical; the beyond-use date is assigned based on documented stability data and is shorter than the historical Geref labeled stability unless specific stability work supports an extension. Patients are instructed on cold-chain handling, reconstitution procedure if relevant, and recognition of temperature excursions warranting pharmacist consultation.

Sermorelin Compounding & Operations

503A compounding

Compounded sermorelin is prepared under 503A on patient-specific prescriptions in state-licensed compounding pharmacies. RonanRx prepares sterile injectable preparations per USP General Chapter <797>, the official compendial standard for sterile pharmaceutical compounding, with documented active ingredient sourcing, gravimetric and analytical verification, sterility and endotoxin testing per the pharmacy's quality-management system, and full lot traceability [usp_797; usp_795]. For any nonsterile preparative steps the corresponding USP General Chapter <795> applies; the finished injectable product is governed by <797> in full.

Because there is no FDA-approved sermorelin product on the U.S. market, FDA's essentially-a-copy-of-an-approved-drug guidance [fda_essentially_a_copy] does not directly constrain compounded sermorelin in the way it constrains compounded copies of currently marketed products. Compounded sermorelin nonetheless operates strictly under the patient-specific 503A framework [fda503a]: every preparation must be linked to a prescription written by a licensed prescriber for an identified patient with a documented clinical reason. RonanRx applies a strict review threshold for sermorelin: compounding is restricted to documented clinical contexts (adult GH insufficiency with biochemical confirmation and prescriber rationale for GHRH stimulation rather than recombinant GH replacement, or other prescriber-documented clinical settings where GHRH-receptor agonism is the rational therapeutic target) [usp_797]. RonanRx does not compound sermorelin for anti-aging, athletic performance, body composition in adults without documented GH insufficiency, sleep optimization, or other off-label consumer indications.

Pharmacist review

Each prescription for compounded sermorelin undergoes pharmacist review prior to dispensing [fda503a]. The review confirms: a documented patient-specific clinical reason for sermorelin (adult GH insufficiency

with biochemical confirmation, GHRH-arginine diagnostic testing supervised by endocrinology, or another prescriber-documented clinical context); absence of contraindications (active malignancy, known or suspected pituitary tumor or sellar mass, hypersensitivity to sermorelin or excipients, pregnancy) [fda_label_geref]; documented baseline IGF-1 with a plan for periodic monitoring; documented baseline glycemic status; and a prescribed regimen with clinical rationale.

RonanRx does not fill sermorelin prescriptions that read as anti-aging, athletic performance, sleep optimization, or general well-being requests without documented clinical context. RonanRx does not operate as a direct-to-consumer sermorelin storefront. Prescriber and patient education materials emphasize that sermorelin is not currently FDA-approved, is not a fountain of youth, and is prohibited by WADA in competitive sport [wada_prohibited_list] [fda503a].

Quality and traceability

Active pharmaceutical ingredient is sourced from FDA-registered facilities with documented certificates of analysis. Each batch is recorded with lot numbers traceable to API source, compounding date, beyond-use date, sterility test result, endotoxin test result, and dispensing pharmacist of record. Finished product lot records are retained per state board of pharmacy retention requirements.

Cold chain

Compounded sterile injectable sermorelin is treated as a cold-chain product per pharmacy stability data. Refrigerated transport is used between the compounding pharmacy and the patient with temperature monitoring through the shipment [usp_797]. Patients are advised to refrigerate the product on arrival, to inspect for temperature excursions, and to contact the pharmacy if cold-chain integrity is in question.

Frequently Asked Questions About Sermorelin

Is sermorelin FDA-approved?

Not currently. Geref (sermorelin acetate, Serono) was FDA-approved in 1990 as a diagnostic test and in 1997 for long-term treatment of idiopathic growth hormone deficiency in children with growth failure [fda_label_geref; prakash1999]. Serono voluntarily withdrew Geref from the U.S. market in 2008 for commercial reasons unrelated to safety or efficacy. There is no FDA-approved sermorelin product available in the United States today.

Is sermorelin a fountain of youth?

No. Short studies in healthy older adults documented IGF-1 elevation and modest body composition changes (1-2 kg lean mass, modest trunk fat reduction) over 8-16 weeks. None measured functional outcomes. The 2007 Annals of Internal Medicine systematic review of growth hormone in healthy older adults [liu2007] concluded that body composition changes are small, functional benefit is unproven, and

adverse events are more common [vittone1997; khorram1997_may]. Sermorelin is not a validated anti-aging therapy [khorram1997_nov; corpas1992].

How does sermorelin work?

Sermorelin is the 29-amino-acid N-terminal fragment of growth hormone-releasing hormone (GHRH). It binds the pituitary GHRH receptor and stimulates pulsatile release of the patient's own growth hormone, which raises serum IGF-1. Because it works through the patient's own pituitary, GH secretion remains pulsatile rather than continuous, mechanistically distinct from direct recombinant growth hormone administration [thorner1986, corpas1992].

What is sermorelin used for in current medicine?

Two main uses persist after the 2008 Geref withdrawal. First, GHRH (1-29), administered as sermorelin or a comparable analog, is a stimulus in the GHRH-arginine diagnostic test for adult GH deficiency, retained as a guideline-recommended option by the 2011 Endocrine Society and 2019 AACE adult GHD guidelines [molitch2011, yuen2019]. Second, compounded sermorelin under 503A is used in adults with documented growth hormone insufficiency on a patient-specific prescription with prescriber rationale for GHRH stimulation rather than recombinant GH replacement [walker2006].

When would RonanRx compound sermorelin?

Only on a patient-specific prescription with documented clinical context, typically adult growth hormone insufficiency with biochemical confirmation, or a prescriber-documented clinical setting where GHRH-axis stimulation is the rational target, plus baseline and follow-up monitoring. RonanRx does not compound sermorelin for anti-aging, athletic performance, body composition in adults without documented GH insufficiency, sleep optimization, or other consumer indications [fda503a].

What are the most common side effects?

Injection-site reactions (erythema, pain, swelling, pruritus), flushing, transient headache, and an expected dose-dependent rise in IGF-1 are most common across the pediatric and adult research literature. Small increases in fasting glucose have been observed in some adult-aging studies [khorram1997_may; khorram1997_nov]. Hypersensitivity reactions including rare anaphylaxis have been reported across the peptide GHRH-analog class [thorner1986; grunt1995; vittone1997].

Is sermorelin allowed in competitive sport?

No. WADA includes growth hormone-releasing factors and GHRH analogs (sermorelin, tesamorelin, CJC-1295) on the prohibited list for both in- and out-of-competition use [wada_prohibited_list]. Athletes subject to WADA testing should not use sermorelin under any circumstances.

Does RonanRx sell compounded sermorelin directly to patients?

No. Compounded sermorelin requires a patient-specific prescription written by a licensed prescriber for an identified patient with documented clinical context, plus pharmacist review before dispensing. RonanRx is not a direct-to-consumer storefront and does not dispense sermorelin for anti-aging, athletic performance, or general well-being requests [fda503a].

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How to Access Sermorelin

Compounded Sermorelin is dispensed under 503A on a patient-specific prescription. Depending on your role, the next step looks different.

FOR PRESCRIBING CLINICIANS

Offer this medication

A pharmacist will follow up within two business days. We'll cover state availability, supported formulations, and what integration looks like for your clinic.

ronanrx.com/request-partnership-call

PATIENT WITH A DOCTOR

Receive your prescription

If your doctor has prescribed Sermorelin, sign up so we can prepare and ship your medication. The signup wizard collects intake and connects you to the prescribing workflow.

ronanrx.com/patients

PATIENT WITHOUT A DOCTOR

Find a partner clinic

RonanRx prescribes through partner clinics — we don't initiate prescriptions on this site. Read how the referral process works and how to find a partner clinic in your state.

ronanrx.com/find-clinic

Other compounds RonanRx makes

This monograph is one of many in the RonanRx formulary. Every compound below is prepared under 503A on a patient-specific prescription. Browse the full catalog at ronanrx.com/medications and ronanrx.com/peptides, or scan the codes at right for each index.

Medications

Peptides

MEDICATIONS (40)

Alpha-Lipoic Acid (ALA) — Antioxidant & mitochondrial
Coenzyme Q10 (CoQ10) — Antioxidant & mitochondrial
Glutathione — Antioxidant & mitochondrial
NAD+ / NMN — Antioxidant & mitochondrial
Compounded Topical Anesthetics (BLT, LET) — Dermatology
Topical Minoxidil — Dermatology
Topical Tretinoin — Dermatology
Compounded Magnesium — Energy & nutritional
Cyanocobalamin — Energy & nutritional
High-Dose Vitamin D — Energy & nutritional
Hydroxocobalamin — Energy & nutritional
Iron (Compounded) — Energy & nutritional
L-Carnitine — Energy & nutritional
Methylcobalamin (B12) — Energy & nutritional
Methylfolate — Energy & nutritional
Anastrozole — Hormone optimization
Clomiphene & Enclomiphene — Hormone optimization
DHEA — Hormone optimization
Estradiol — Hormone optimization
Estriol — Hormone optimization
Human Chorionic Gonadotropin (HCG) — Hormone optimization
Pregnenolone — Hormone optimization
Progesterone — Hormone optimization
Testosterone — Hormone optimization
Compounded Metformin — Metabolic & weight
Compounded Semaglutide — Metabolic & weight
Compounded Tirzepatide — Metabolic & weight
Lipotropic Injection (MIC, MICC) — Metabolic & weight
Low-Dose Naltrexone (LDN) — Metabolic & weight
Naltrexone-Bupropion Combination — Metabolic & weight
Topiramate — Metabolic & weight
Bremelanotide / PT-141 — Sexual health
Compounded Sildenafil — Sexual health
Compounded Tadalafil — Sexual health
Trimix Injection — Sexual health
Compounded Gabapentin — Sleep & recovery
Compounded Melatonin — Sleep & recovery
Compounded T3 (Liothyronine) — Thyroid
Compounded T3/T4 Combinations — Thyroid
Compounded T4 (Levothyroxine) — Thyroid

PEPTIDES (21)

Sermorelin — Available now

Tesamorelin — Available now

AOD-9604 — Growth-hormone axis (under FDA review)

CJC-1295 — Growth-hormone axis (under FDA review)

GHRP-2 / GHRP-6 — Growth-hormone axis (under FDA review)

Hexarelin — Growth-hormone axis (under FDA review)

Ipamorelin — Growth-hormone axis (under FDA review)

MK-677 / Ibutamoren — Growth-hormone axis (under FDA review)

5-Amino 1MQ — Metabolic & longevity (under FDA review)

Epitalon / Epithalon — Metabolic & longevity (under FDA review)

MOTS-C — Metabolic & longevity (under FDA review)

Thymosin Alpha-1 / Thymalin — Metabolic & longevity (under FDA review)

DSIP, Delta Sleep-Inducing Peptide — Neuro & cognitive (under FDA review)

Selank — Neuro & cognitive (under FDA review)

Semax — Neuro & cognitive (under FDA review)

Vasoactive Intestinal Peptide (VIP) — Neuro & cognitive (under FDA review)

BPC-157 — Tissue repair (under FDA review)

KPV — Tissue repair (under FDA review)

LL-37 — Tissue repair (under FDA review)

Pentadeca Arginate (PDA) — Tissue repair (under FDA review)

TB-500 / Thymosin Beta-4 — Tissue repair (under FDA review)