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PERSONALIZED MEDICINE

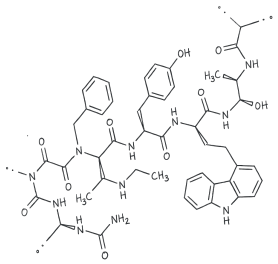
CLINICAL MONOGRAPH · AVAILABLE NOW

Tesamorelin

GHRH analog, FDA-approved as Egrifta

Tesamorelin is a once-daily (or, in the newer Egrifta WR formulation, once-weekly) subcutaneous injection that stimulates the body's own growth hormone [fda_label_egrifta; fda_label_egrifta_wr]. The FDA approved it in November 2010 as Egrifta for adults with HIV who have built up excess abdominal fat as a complication of antiretroviral therapy, a condition called HIV-associated lipodystrophy. A reformulated daily product (Egrifta SV) was approved in 2019, and a once-weekly version (Egrifta WR) was approved in 2024.

It works by mimicking a brain hormone called GHRH, which tells the pituitary gland to release pulses of growth hormone [falutz2007]. Across two large phase 3 trials in HIV-associated lipodystrophy, tesamorelin reduced visceral abdominal fat by roughly 15-18% over 26 weeks [falutz2010_jaids]. It is the only FDA-approved medicine for that specific condition. Outside HIV-associated lipodystrophy, tesamorelin is not FDA-approved for any indication, including weight loss, anti-aging, or general body composition.



EVIDENCE POSTURE | FDA APPROVED | WELL STUDIED | REVIEWED **2026-05-11**

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

Contents

Click any section to jump there. Page numbers update on render.

FOR CLINICIANS

Tesamorelin is a synthetic 44-amino-acid GHRH analog modified at the N-terminus with a trans-3-hexenoyl group that protects against DPP-IV cleavage and extends plasma exposure relative to native GHRH (1-44). Mechanism: tesamorelin binds the pituitary GHRH receptor, stimulating pulsatile endogenous growth hormone release and a downstream rise in serum IGF-1; the preserved pulsatile pattern is mechanistically distinct from exogenous recombinant human growth hormone administration [stanley2011, makimura2011]. FDA-approved in November 2010 as Egrifta on the basis of two phase 3 randomized double-blind placebo-controlled trials in adults with HIV-associated abdominal lipodystrophy [falutz2007, falutz2010_jaids]; reformulated as Egrifta SV in 2019 (improved stability, four-week beyond-use date post-reconstitution at 2-8 degrees C) and as once-weekly Egrifta WR in 2024 [fda_label_egrifta].

Across the pivotal trials, tesamorelin 2 mg subcutaneously daily produced approximately 15-18% reduction in visceral adipose tissue by CT at 26 weeks vs minimal change on placebo, with reductions also in trunk fat, waist circumference, and the trunk-to-limb fat ratio [falutz2007, falutz2010_jaids, falutz2008]. Subsequent work in HIV-associated nonalcoholic fatty liver disease [stanley2014, stanley2019] demonstrated significant absolute reductions in hepatic fat content by magnetic resonance spectroscopy, with the Lancet HIV trial reporting fibrosis non-progression and favorable hepatic transcriptomic and proteomic signatures in subsequent translational analyses [fourman2020, stanley2021_cid]. Mechanistic and pharmacology studies have characterized the pulsatile GH response and IGF-1 dynamics in healthy adults [stanley2011] and in adults with HIV [falutz2010_jcem, makimura2011]. Phase 2 evaluation in type 2 diabetes [clemmons2017] demonstrated reductions in visceral adipose tissue and triglycerides without clinically meaningful glycemic worsening in a 12-month study. Adverse events are dominated by injection-site reactions, arthralgia, peripheral edema, and an expected rise in IGF-1; the elevation in IGF-1 mandates monitoring and dose interruption if levels exceed two standard deviations above age- and sex-adjusted normal. Compounded tesamorelin for HIV-associated lipodystrophy is essentially a copy of the manufactured product and is restricted under FDA's 503A copy-of-an-approved-drug guidance [fda_essentially_a_copy] [fda_label_egrifta; fda_label_egrifta_sv; fda_label_egrifta_wr].

Why Personalized Tesamorelin

Egrifta's 2 mg daily regimen was calibrated against an averaged HIV-associated lipodystrophy trial population. It was not set for your baseline IGF-1, your mannitol or other excipient sensitivities, your tolerance for injection-site reactions, the cadence your pituitary actually responds on, or the supply windows when manufactured Egrifta SV or Egrifta WR is short. The labeled dose interruption rule (IGF-1 above two standard deviations of the age- and sex-adjusted normal) only matters if the strength on the vial can be matched to where your IGF-1 actually sits.

That fit work is what a 503A compounding pharmacy can legally do for tesamorelin, on a narrow lane. The molecule is the same 44-amino-acid GHRH analog the FDA reviewed. With a prescriber's documented clinical rationale, the preparation can be lyophilized at a strength the manufactured Egrifta-family products do not offer, formulated without an excipient the patient reacts to, or dispensed to bridge a documented manufactured-product supply interruption. What RonanRx will not do is compound tesamorelin for anti-aging, general body composition in adults without HIV, athletic performance, or as a microgram-dose cocktail with other GHRH or GHRP peptides. Those uses sit outside the labeled indication and outside FDA's essentially-a-copy guidance.

This is the older arrangement: a doctor writes for a named patient, a licensed pharmacist prepares it, and the dispensing record is auditable. Modern oversight is what keeps that arrangement honest.

Quick Facts About Tesamorelin

Category: Synthetic growth hormone-releasing hormone (GHRH) analog

Active ingredient: Tesamorelin acetate, a 44-amino-acid analog of human GHRH (1-44) bearing an N-terminal trans-3-hexenoyl modification that confers resistance to dipeptidyl peptidase-IV (DPP-IV) degradation

FDA-approved branded forms: Egrifta (approved November 10, 2010), Egrifta SV (2019 reformulation with 4-week stability post-reconstitution), and Egrifta WR (2024 once-weekly subcutaneous reformulation), all indicated for reduction of excess abdominal fat in HIV-infected patients with lipodystrophy

Route: Subcutaneous injection, daily for Egrifta and Egrifta SV; once weekly for Egrifta WR

Evidence posture: Two phase 3 trials in HIV-associated abdominal lipodystrophy [falutz2007, falutz2010_jaids] established efficacy of the manufactured product, with parallel evidence for liver fat reduction in HIV-associated NAFLD [stanley2014, stanley2019]

FDA-approval status: Manufactured Egrifta, Egrifta SV, and Egrifta WR are FDA-approved for HIV-associated abdominal lipodystrophy only. Compounded tesamorelin is not FDA-approved and is not approved for any non-HIV indication.

Compounded under: 503A, patient-specific prescription only, and only when the manufactured Egrifta/Egrifta SV/Egrifta WR product cannot meet a documented clinical need

Important compounding caution: Compounded tesamorelin for HIV-associated lipodystrophy is essentially a copy of an FDA-approved product unless the prescriber documents a patient-specific reason the manufactured product cannot be used (excipient sensitivity, dose individualization, route or strength not commercially available). Compounded tesamorelin for anti-aging, body composition in adults without HIV, or other off-label indications is outside the FDA-approved labeling and not supported by the published efficacy program.

SPECIALS: PATIENT-SPECIFIC PRESCRIPTION ONLY

Tesamorelin 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 Tesamorelin?

Tesamorelin is a synthetic 44-amino-acid analog of human growth hormone-releasing hormone (GHRH, residues 1-44). The molecule carries an N-terminal trans-3-hexenoyl modification that protects against cleavage by dipeptidyl peptidase-IV (DPP-IV), the principal degradation pathway for endogenous GHRH. This modification extends the plasma half-life sufficiently to permit once-daily subcutaneous administration of the original Egrifta and Egrifta SV products, and once-weekly administration of Egrifta WR [fda_label_egrifta].

Tesamorelin was developed by Theratechnologies under the development name TH9507 and licensed for U.S [fda_label_egrifta]. commercialization to EMD Serono. The FDA approved Egrifta on November 10, 2010 for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. A reformulated daily product (Egrifta SV) was approved in 2019 and offers a longer in-use beyond-use date after reconstitution, simplifying patient handling. A once-weekly subcutaneous reformulation (Egrifta WR) was approved by the FDA in 2024 for the same indication.

The drug substance in all three approved products is tesamorelin acetate. Reconstituted product is administered by subcutaneous injection in the abdomen, with site rotation. Tesamorelin is supplied as a lyophilized powder for reconstitution with sterile water for injection (Egrifta SV) or with the manufacturer-supplied diluent (Egrifta WR), per labeling [fda_label_egrifta_sv, fda_label_egrifta_wr] [fda_label_egrifta].

How Tesamorelin Works

Tesamorelin binds and activates the GHRH receptor on pituitary somatotropes, stimulating pulsatile endogenous release of growth hormone (GH). The downstream rise in serum insulin-like growth factor-1 (IGF-1) mediates many of the peripheral metabolic effects, including lipolysis in visceral adipose tissue. Because tesamorelin acts through the patient's own pituitary, the resulting GH secretion preserves the physiologic pulsatile pattern, which is mechanistically distinct from continuous exposure produced by direct administration of recombinant human GH [stanley2011, makimura2011].

The N-terminal trans-3-hexenoyl modification confers resistance to DPP-IV proteolysis, the principal degradation route for endogenous GHRH (1-44). This molecular protection extends the plasma half-life of tesamorelin to approximately 26-38 minutes, sufficient to generate a discrete and sustained GH secretory response after each subcutaneous dose. With repeated daily dosing, IGF-1 levels rise to a new steady state typically within 2 weeks and decline back toward baseline within weeks of discontinuation.

Net clinical effects in adults with HIV-associated lipodystrophy include preferential reduction of visceral adipose tissue, smaller reductions in trunk subcutaneous fat, modest changes in lipid profile, and an

expected dose-dependent rise in IGF-1 [falutz2007, falutz2010_jaids]. Effects on liver fat are well characterized in HIV-associated NAFLD [stanley2014, stanley2019].

Biological Role of Tesamorelin

Growth hormone-releasing hormone is the master positive regulator of the somatotrope axis. Hypothalamic GHRH secretion 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 (increases in lean mass, reductions in visceral adiposity, modulation of insulin sensitivity and lipid handling), and tissue-specific effects on bone, skeletal muscle, and immune function.

In HIV-associated lipodystrophy, the somatotrope axis is dysregulated: many adults exhibit reduced GH pulse amplitude and reduced 24-hour integrated GH secretion in the context of excess visceral adiposity, which itself feeds back to suppress GH secretion via free fatty acid and hyperinsulinemia-mediated mechanisms. Tesamorelin restores pulsatile GH secretion at the level of the pituitary somatotrope, distinct from direct exogenous administration of recombinant GH; the rationale for tesamorelin in HIV-associated lipodystrophy is therefore physiologic restoration of a suppressed endogenous axis [rochira2017, jain2013].

Detailed Mechanism of Tesamorelin

Endogenous GHRH is a 44-amino-acid hypothalamic peptide secreted into hypophyseal portal blood and is the principal positive regulator of pituitary GH secretion. GHRH (1-44) is rapidly inactivated in plasma by DPP-IV cleavage of the N-terminal Tyr-Ala dipeptide, yielding GHRH (3-44) with markedly reduced potency. The trans-3-hexenoyl modification of tesamorelin's N-terminal tyrosine creates steric hindrance that protects against this cleavage, preserving GHRH-receptor agonist activity in vivo [stanley2011].

In healthy adults, Stanley and colleagues (2011) used overnight frequent venous sampling to demonstrate that tesamorelin restored pulsatile GH secretion to a pattern resembling that of younger adults, with increased mean GH concentration, increased peak amplitude, and preserved pulse frequency, accompanied by improved insulin sensitivity by frequently sampled IV glucose tolerance testing [stanley2011]. Makimura and colleagues extended this analysis to show a relationship between adiponectin and endogenous GH pulse parameters in response to GHRH-analog stimulation [makimura2011]. In adults with HIV-associated lipodystrophy, parallel work characterized the IGF-1 dynamics on daily tesamorelin and the relationship between IGF-1 exposure and visceral fat response [falutz2010_jcem, stanley2011_aids].

Effects on liver are particularly well characterized. Stanley and colleagues (2014, JAMA) randomized 50 adults with HIV and abdominal fat accumulation plus elevated hepatic fat to tesamorelin 2 mg daily versus placebo for six months and reported a relative reduction in hepatic fat content of approximately one-third by proton magnetic resonance spectroscopy [stanley2014]. The phase 3 Lancet HIV trial [stanley2019] randomized 61 adults with HIV-associated NAFLD to tesamorelin or placebo for one year, demonstrating

an absolute reduction in hepatic fat fraction and a lower rate of fibrosis progression on tesamorelin. Subsequent translational work characterized tesamorelin's effects on hepatic transcriptomic signatures [fourman2020], targeted proteomic and transcriptomic responder pathways [stanley2021_cid], and circulating markers of immune activation [stanley2021_cid]. Reductions in fibroblast growth factor 21 paralleling liver fat reduction were demonstrated by Braun and colleagues [braun2017].

Pharmacokinetically, tesamorelin is administered subcutaneously; the published population PK analyses identify a single-compartment model with first-order absorption and a terminal half-life on the order of 26-38 minutes after subcutaneous administration in adults with HIV. Clearance is via proteolytic catabolism; cytochrome P450 enzymes are not implicated. Pulsatile endogenous GH secretion provides the durable pharmacodynamic signal that supports daily (and, in the WR formulation, weekly) dosing despite the short peptide half-life [stanley2011, falutz2010_jcem].

Tesamorelin Research History

Tesamorelin (TH9507) was developed by the Canadian biotechnology company Theratechnologies during the 2000s as a stable analog of human GHRH (1-44) intended to restore physiologic pulsatile GH secretion in clinical contexts where the axis is suppressed. Phase 2 evaluation in HIV-associated lipodystrophy demonstrated reductions in visceral adipose tissue and supported pivotal phase 3 development. The first pivotal trial [falutz2007] published in the New England Journal of Medicine in December 2007 randomized 412 HIV-infected adults with abdominal fat accumulation to tesamorelin 2 mg subcutaneously daily versus placebo for 26 weeks; visceral adipose tissue by CT decreased 15.2% with tesamorelin versus 5.0% increase on placebo, with parallel reductions in trunk fat and triglycerides and an expected rise in IGF-1 [fda_label_egrifta].

An extension phase reported by Falutz and colleagues [falutz2008] in AIDS in 2008 characterized long-term safety and efficacy in patients continuing tesamorelin through 52 weeks. The second pivotal phase 3 trial [falutz2010_jaids], published in the Journal of Acquired Immune Deficiency Syndromes in 2010, randomized 404 HIV-infected adults to tesamorelin or placebo for 26 weeks with a 26-week safety extension; visceral adipose tissue decreased approximately 18% on tesamorelin versus a modest increase on placebo, with improvements in trunk-to-limb fat ratio and waist circumference. A companion publication [falutz2010_jcem] reported the IGF-1 dynamics and metabolic profile across the development program. Pooled analyses [stanley2012] integrated phase 3 data to characterize the predictors of visceral fat response and the relationship between reduced visceral adiposity and metabolic outcomes including triglycerides, adiponectin, and inflammatory markers [stanley2011_aids]. On November 10, 2010, FDA approved Egrifta for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy [fda_label_egrifta].

Subsequent clinical development extended tesamorelin into HIV-associated nonalcoholic fatty liver disease. Stanley and colleagues (2014, JAMA) reported that tesamorelin reduced hepatic fat content by proton magnetic resonance spectroscopy in HIV-infected adults with abdominal adiposity and hepatic steatosis

over six months [stanley2014]. The phase 3 Lancet HIV trial published by Stanley and colleagues in 2019 [stanley2019] randomized 61 adults with HIV-associated NAFLD to tesamorelin or placebo for 12 months, demonstrating absolute reduction in hepatic fat fraction (-4.1% on tesamorelin versus +0.9% on placebo at 12 months) and a lower rate of fibrosis progression [fda_label_egrifta]. Translational work characterized tesamorelin-responsive hepatic transcriptomic signatures [fourman2020], targeted proteomic and transcriptomic responder pathways and reductions in circulating markers of immune activation [stanley2021_cid], reductions in FGF21 paralleling liver fat reduction [braun2017], and effects on muscle composition [fourman2019]. The Lake and colleagues 2021 analysis [lake2021] documented improvements in fat quality independent of fat quantity changes.

Cognitive aging studies have evaluated GHRH-analog stimulation in older adults with mild cognitive impairment. The Baker and colleagues 2012 trial [baker2012] in Archives of Neurology randomized 152 older adults (87 with mild cognitive impairment and 65 cognitively intact) to 20 weeks of daily subcutaneous tesamorelin or placebo and reported improvements in executive function, with the Friedman and colleagues 2013 substudy [friedman2013] using magnetic resonance spectroscopy to document GABA, N-acetylaspartate, and myo-inositol changes consistent with neuroprotection. These trials are mechanistic and do not establish tesamorelin as a treatment for cognitive disorders. Russo and colleagues 2024 [russo2024] characterized tesamorelin efficacy and safety in HIV-infected adults on integrase inhibitors, and Ellis and colleagues 2025 [ellis2025] reported effects on neurocognitive performance in adults with HIV and abdominal obesity. Reformulation activity produced Egrifta SV (FDA-approved 2019 with improved post-reconstitution stability) and Egrifta WR (FDA-approved 2024 as a once-weekly subcutaneous product) [fda_label_egrifta_sv, fda_label_egrifta_wr] [fda_label_egrifta].

Tesamorelin Timeline

- **2007** • Falutz et al [falutz2007]. publish phase 3 pivotal trial of tesamorelin in HIV-associated lipodystrophy (N=412, 26 weeks) in NEJM, VAT reduced 15.2% vs +5.0% on placebo
- **2008** • Falutz et al [falutz2008]. report long-term (52-week) safety and efficacy extension in AIDS
- **2010** • Second pivotal phase 3 trial (Falutz et al., JAIDS, N=404) plus safety extension confirms 18% VAT reduction at 26 weeks [falutz2010_jaids]
- **2010** • Companion phase 3 publication (Falutz et al., JCEM) characterizes IGF-1 dynamics and metabolic profile [falutz2010_jcem]
- **2010** • FDA approves Egrifta (tesamorelin) for reduction of excess abdominal fat in HIV-infected patients with lipodystrophy (November 10, 2010) [fda_label_egrifta]
- **2011** • Stanley et al [stanley2011]. (JCEM) characterize tesamorelin effect on endogenous GH pulsatility and insulin sensitivity in healthy men

2011 • Makimura et al [makimura2011]. (Growth Horm IGF Res), relationship of adiponectin to endogenous GH pulse parameters with GHRH-analog stimulation

2011 • Stanley et al [stanley2011_aids]. (AIDS), tesamorelin effects on inflammatory markers and relationship to visceral adipose reduction

2011 • Dhillon (Drugs) review of tesamorelin for HIV-associated lipodystrophy [dhillon2011]

2012 • Stanley et al [stanley2012]. (Clin Infect Dis), pooled phase 3 analysis: visceral adiposity reduction associated with improved metabolic profile

2012 • Baker et al [baker2012]. (Arch Neurol), controlled trial of daily tesamorelin in mild cognitive impairment and healthy older adults; improvements in executive function over 20 weeks

2013 • Friedman et al [friedman2013]. (JAMA Neurol), GHRH-analog effects on brain GABA, N-acetylaspartate, and myo-inositol by magnetic resonance spectroscopy in MCI and healthy aging

2014 • Stanley et al [stanley2014]. (JAMA), tesamorelin reduces hepatic fat content by proton MR spectroscopy in HIV-associated NAFLD over 6 months

2017 • Clemmons et al [clemmons2017]. (PLoS One), phase 2 safety and metabolic effects of tesamorelin in adults with type 2 diabetes (12 months)

2017 • Braun et al [braun2017]. (Growth Horm IGF Res), FGF21 decreases after liver fat reduction with tesamorelin

2017 • Adrian et al [adrian2017]. (AIDS), visceral fat reduction with tesamorelin associated with improved liver enzymes in HIV

2019 • FDA approves Egrifta SV (reformulated daily product with 4-week post-reconstitution stability) [fda_label_egrifta_sv]

2019 • Stanley et al [stanley2019]. (Lancet HIV), phase 3 trial of tesamorelin in HIV-associated NAFLD over 12 months: significant reduction in hepatic fat and lower rate of fibrosis progression

2019 • Fourman et al [fourman2019]. (J Frailty Aging), tesamorelin decreases muscle fat and increases muscle area in adults with HIV

2020 • Fourman et al [fourman2020]. (JCI Insight), hepatic transcriptomic signatures responsive to tesamorelin in HIV-associated NAFLD

2021 • Lake et al [lake2021]. (AIDS), tesamorelin improves fat quality independent of fat quantity changes

2021 • Stanley et al [stanley2021_cid]. (Clin Infect Dis), GHRH reduces circulating markers of immune activation in parallel with hepatic immune-pathway effects in HIV-associated NAFLD

2022 • Fourman and Grinspoon (JCEM) review approach to the patient with lipodystrophy including tesamorelin pharmacology [fourman2022]

2024 • FDA approves Egrifta WR, once-weekly subcutaneous tesamorelin formulation for HIV-associated lipodystrophy [fda_label_egrifta_wr]

2024 • Russo et al [russo2024]. (AIDS), tesamorelin efficacy and safety in HIV-infected adults on integrase inhibitor regimens

2025 • Ellis et al [ellis2025]. (J Infect Dis), effects of tesamorelin on neurocognitive impairment in persons with HIV and abdominal obesity

Clinical Contexts for Tesamorelin

HIV-associated lipodystrophy with excess abdominal fat in adults FDA APPROVED

FDA-approved indication for Egrifta, Egrifta SV, and Egrifta WR. This is the only FDA-approved indication for tesamorelin.

Two pivotal phase 3 randomized double-blind placebo-controlled trials [falutz2007, falutz2010_jaids] in HIV-infected adults with abdominal fat accumulation demonstrated approximately 15-18% reduction in visceral adipose tissue by CT at 26 weeks on tesamorelin 2 mg subcutaneously daily versus minimal change on placebo. The long-term extension data [falutz2008] supported continued efficacy through 52 weeks with discontinuation associated with regain of visceral fat. Pooled analyses [stanley2012] characterized the relationship between visceral fat reduction and metabolic profile (triglycerides, adiponectin, inflammatory markers [stanley2011_aids]). Egrifta SV (2019 reformulation) and Egrifta WR (2024, once-weekly) carry the same labeled indication [fda_label_egrifta; fda_label_egrifta_sv; fda_label_egrifta_wr].

Branded product: Egrifta, Egrifta SV, and Egrifta WR (tesamorelin acetate, Theratechnologies)

HIV-associated nonalcoholic fatty liver disease WELL STUDIED

Studied in two randomized controlled trials; not an FDA-approved indication.

Stanley et al. (2014, JAMA) [stanley2014] randomized 50 adults with HIV, abdominal fat accumulation, and hepatic steatosis to tesamorelin 2 mg daily versus placebo for 6 months; hepatic fat content by proton magnetic resonance spectroscopy decreased relatively by approximately one-third. The phase 3 Lancet HIV trial [stanley2019] randomized 61 adults with HIV-associated NAFLD to 12 months of tesamorelin versus placebo, demonstrating absolute reduction in hepatic fat fraction and a lower rate of fibrosis progression. Translational analyses characterized tesamorelin-responsive hepatic transcriptomic signatures [fourman2020], reductions in circulating immune-activation markers [stanley2021_cid], and reductions in FGF21 paralleling hepatic fat reduction [braun2017].

Cognitive function in mild cognitive impairment and healthy older adults WELL STUDIED

Studied in a single controlled trial with imaging substudy; mechanistic only and does not establish tesamorelin as a treatment for cognitive disorders.

Baker and colleagues (2012, Arch Neurol) [baker2012] randomized 152 older adults (87 with amnestic mild cognitive impairment, 65 cognitively intact) to 20 weeks of subcutaneous tesamorelin 1 mg daily or placebo and reported improvements in executive function on tesamorelin in both groups. The companion magnetic resonance spectroscopy substudy [friedman2013] documented increases in brain GABA and changes in N-acetylaspartate and myo-inositol consistent with neuroprotective signaling. Neither trial supports tesamorelin as an approved treatment for cognitive impairment, and the FDA has not approved tesamorelin for any cognitive indication.

Body composition in HIV-infected adults on integrase inhibitor regimens WELL STUDIED

Post-marketing population-specific evaluation; consistent with the FDA-approved labeling.

Russo and colleagues (2024, AIDS) [russo2024] reported efficacy and safety of tesamorelin in HIV-infected adults on contemporary integrase strand transfer inhibitor regimens, the dominant antiretroviral class in current practice. Findings support continued relevance of tesamorelin in the current treatment era. Fourman and colleagues (2019, J Frailty Aging) [fourman2019] reported decreased intramuscular adipose tissue and increased muscle cross-sectional area on tesamorelin.

Neurocognitive performance in adults with HIV and abdominal obesity WELL STUDIED

Studied in a randomized trial; tesamorelin is not FDA-approved for cognitive endpoints.

Ellis and colleagues (2025, J Infect Dis) [ellis2025] reported effects of tesamorelin on neurocognitive performance in adults with HIV and abdominal obesity. The result extends the body composition rationale to a neurocognitive substudy population but does not establish a cognitive indication; tesamorelin is not FDA-approved for cognitive function in any population.

Off-Label Uses of Tesamorelin

Visceral adiposity reduction in adults with type 2 diabetes (without HIV) WELL STUDIED

Studied in a single phase 2 trial; not an FDA-approved indication.

Clemmons and colleagues (2017, PLoS One) [clemmons2017] randomized adults with type 2 diabetes to tesamorelin or placebo for 12 months and reported reductions in visceral adipose tissue and triglycerides without clinically meaningful changes in HbA1c or fasting glucose. The trial demonstrated tolerability but did not lead to an expansion of the FDA-approved indication beyond HIV-associated lipodystrophy.

Body composition and anti-aging in adults without HIV EMERGING

Not an FDA-approved indication. The published evidence base for tesamorelin is confined to HIV-associated lipodystrophy, HIV-associated NAFLD, type 2 diabetes (phase 2), and cognitive substudies in older adults; routine use for body composition or anti-aging in adults without HIV is outside the published trial populations.

Outside the FDA-approved labeling, anecdotal use of tesamorelin for body composition or anti-aging in adults without HIV has been promoted in the consumer market. The published efficacy program does not establish benefit in this population, and the FDA has not approved tesamorelin for any non-HIV indication [fda_essentially_a_copy]. RonanRx does not compound tesamorelin for body composition or anti-aging indications [fda_label_egrifta_wr].

FDA-Approved Uses of Tesamorelin

Brand	Indication	Year	Route
Egrifta	Reduction of excess abdominal fat in HIV-infected patients with lipodystrophy	2010	Subcutaneous injection, once daily
Egrifta SV	Reduction of excess abdominal fat in HIV-infected patients with lipodystrophy (reformulated daily product with improved post-reconstitution stability)	2019	Subcutaneous injection, once daily
Egrifta WR	Reduction of excess abdominal fat in HIV-infected patients with lipodystrophy (once-weekly reformulation)	2024	Subcutaneous injection, once weekly

The FDA-approved manufactured products are Egrifta (approved November 10, 2010 for HIV-associated abdominal lipodystrophy), Egrifta SV (2019 reformulated daily product with a four-week beyond-use date after reconstitution under refrigeration), and Egrifta WR (2024 once-weekly subcutaneous formulation). All three products share the same labeled indication: reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. The drug substance is tesamorelin acetate in each product; the products differ in formulation, reconstitution procedure, and dosing frequency [fda_label_egrifta].

Labeled limitations of use state that the long-term cardiovascular safety of tesamorelin has not been established, that tesamorelin is not indicated for weight loss, and that the effect of tesamorelin on disease progression of HIV-associated lipodystrophy is not known [fda_label_egrifta; fda_label_egrifta_sv; fda_label_egrifta_wr]. Discontinuation is associated with re-accumulation of visceral fat; long-term continuation must be weighed against safety considerations including IGF-1 elevation and glucose intolerance signal.

Compounded Tesamorelin (503A)

Tesamorelin is FDA-approved as Egrifta, Egrifta SV, and Egrifta WR for one indication only: reduction of excess abdominal fat in HIV-infected patients with lipodystrophy [fda_label_egrifta_sv; fda_label_egrifta_wr]. Compounded tesamorelin under 503A is highly restricted in this regulatory landscape. FDA's guidance on compounded drug products that are essentially copies of approved drug products [fda_essentially_a_copy] limits compounding of a drug that is commercially available except when the prescriber documents a patient-specific clinical need that the manufactured product cannot meet. Acceptable reasons typically fall into three categories: (1) documented sensitivity to a component of the manufactured Egrifta SV or Egrifta WR formulation; (2) a strength or concentration not commercially available that is medically necessary; or (3) a documented supply interruption of the manufactured product.

RonanRx compounds tesamorelin only on a patient-specific prescription with documented clinical rationale meeting one of these categories for an adult with HIV-associated lipodystrophy or a comparable medical need that the manufactured Egrifta-family products cannot accommodate. Compounded tesamorelin is not dispensed for anti-aging, general body composition in adults without HIV, athletic performance, or other off-label indications. These uses sit outside the FDA-approved labeling and outside the published efficacy program for tesamorelin; compounding pharmacies that dispense tesamorelin for these indications operate outside the framework of section 503A as interpreted by FDA's essentially-a-copy guidance [fda503a].

Compounded tesamorelin preparations are typically dispensed as lyophilized powder for reconstitution prior to subcutaneous injection. The compounded preparation is not bioequivalent to Egrifta, Egrifta SV, or Egrifta WR; clinicians and patients should understand that PK/PD characteristics of a compounded preparation may differ from published manufactured-product data, particularly when excipients, lyophilization conditions, or container closure differ from the reference product. The published phase 3 efficacy evidence for tesamorelin [falutz2007, falutz2010_jaids, stanley2019] was generated with the manufactured product and does not transfer to compounded preparations without separate stability, potency, and tolerability evaluation [fda_label_egrifta_sv].

Tesamorelin Formulations and Routes

Form	Concentration	Description
Sterile lyophilized powder for subcutaneous injection (compounded)	Custom, typically reconstituted to deliver 1-2 mg per daily subcutaneous dose on a patient-specific prescription	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 and matched to the patient's clinical profile. Beyond-use dating follows USP <797> requirements and pharmacy stability data.

Form	Concentration	Description
Manufactured Egrifta SV	1 mg per delivered dose after reconstitution (2 mg daily total typically administered as two 1 mg injections, per labeling)	FDA-approved 2019 reformulated daily product supplied as lyophilized powder for reconstitution with sterile water for injection. Reconstituted product is stable for up to four weeks under refrigeration, simplifying patient handling compared with the original Egrifta product.
Manufactured Egrifta WR	Once-weekly subcutaneous dose per current FDA labeling	FDA-approved 2024 once-weekly subcutaneous reformulation supplied as lyophilized powder reconstituted with the manufacturer-supplied diluent. Reduces injection burden from daily to weekly administration for the labeled indication.

Routes used in published literature: subcutaneous.

Tesamorelin Dosing

Route	Population	Range	Duration	Study type
Subcutaneous	Adults with HIV-associated lipodystrophy (Egrifta and Egrifta SV labeled regimen)	2 mg subcutaneously once daily, injected into the abdomen with site rotation	Continued use balanced against IGF-1 elevation and tolerability; discontinuation is associated with re-accumulation of visceral fat	FDA-approved labeled regimen
Subcutaneous	Adults with HIV-associated lipodystrophy (Egrifta WR labeled regimen)	Once-weekly subcutaneous dose per current Egrifta WR labeling	Continued use balanced against IGF-1 elevation and tolerability	FDA-approved labeled regimen following 2024 approval of Egrifta WR
Subcutaneous	Adults with HIV-associated NAFLD (investigational use in published trials)	2 mg subcutaneously once daily as used in the Stanley et al. 2014 (6 months) and 2019 (12 months) trials	6-12 months in published trials	Randomized controlled trial dosing (investigational)
Subcutaneous	Older adults with mild cognitive impairment or	1 mg subcutaneously once daily as used in the Baker et al. 2012 trial	20 weeks in published trial	Randomized controlled trial dosing (investigational)

Route	Population	Range	Duration	Study type
	healthy aging (investigational)			

Doctor-prescribed only. The FDA-approved daily regimen for Egrifta and Egrifta SV is 2 mg subcutaneously once daily into the abdomen with site rotation. The 2024 Egrifta WR product is administered subcutaneously once weekly per its label [fda_label_egrifta]. Treatment effect on visceral fat is observable by approximately 13 weeks and reaches a plateau over the 26-week pivotal trial period; continued dosing is required to maintain effect, with discontinuation associated with re-accumulation of visceral fat [falutz2007, falutz2010_jaids].

IGF-1 must be monitored at baseline and periodically on therapy. Per labeling, IGF-1 levels exceeding two standard deviations above the age- and sex-adjusted normal range should prompt dose interruption or discontinuation given the theoretical concern for IGF-1-mediated adverse outcomes including potential effects on neoplasia. Compounded tesamorelin should mirror the manufactured-product regimen unless the prescriber documents a patient-specific reason for variance [fda_label_egrifta_sv; fda_label_egrifta_wr].

Tesamorelin Safety

Tesamorelin safety is characterized primarily by injection-site reactions, arthralgia, peripheral edema, paresthesia, hypoesthesia, myalgia, and an expected dose-dependent rise in IGF-1 [1][3][2] [2][6]. Across the pivotal phase 3 trials and the safety extensions, injection-site reactions were the most common adverse event, occurring in approximately 25% of tesamorelin-treated participants versus a lower rate on placebo; most were mild and did not lead to discontinuation. Arthralgia and peripheral edema were the most common non-injection-site adverse events at incidence above placebo. Hypersensitivity reactions including rash, urticaria, and rare anaphylaxis have been reported in post-marketing surveillance.

The IGF-1 elevation is a class-relevant labeling consideration. Tesamorelin produces a sustained rise in serum IGF-1 reflecting endogenous GH secretion; labeling recommends IGF-1 monitoring at baseline and periodically with dose interruption if IGF-1 exceeds two standard deviations above the age- and sex-adjusted normal range. Glucose intolerance is a labeled concern: across the phase 3 program, small increases in fasting glucose and 2-hour glucose on oral glucose tolerance testing were observed in some participants, with rare progression to diabetes [1][3]. Tesamorelin should not be used in patients with active malignancy, and known or suspected pituitary tumor or other CNS tumor is a contraindication [2][6].

Long-term cardiovascular safety has not been established. The labeled population is HIV-infected adults with lipodystrophy, a population with elevated baseline cardiovascular risk in whom the contribution of tesamorelin per se cannot be separated from background risk. Effects on liver enzymes are typically favorable in HIV-associated NAFLD populations [1][6][1][3][1][9]. Effects on body composition include decreased

intramuscular adipose tissue and increased muscle cross-sectional area [18] and improvements in fat quality independent of fat quantity [21]. Pharmacovigilance literature relevant to compounded peptide therapy generally cautions against compounded preparations dispensed outside documented patient-specific clinical need; the published clinical evidence for tesamorelin is generated with manufactured product and does not transfer to compounded preparations without separate stability and potency data [262728].

Contraindications

Tesamorelin is contraindicated in patients with disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor or surgery, head irradiation, or head trauma, populations in whom endogenous somatotrope function may be insufficient to support a meaningful response. Tesamorelin is contraindicated in patients with active malignancy (either newly diagnosed or recurrent), in patients with known hypersensitivity to tesamorelin or to mannitol (an excipient in the manufactured product), and in pregnancy.

Caution applies in patients with diabetes mellitus, glucose intolerance, or risk factors for diabetes given the labeled glucose intolerance signal; in patients with a history of pancreatitis; and in patients receiving concomitant therapies known to affect glucose metabolism. Tesamorelin should be discontinued in patients who develop signs or symptoms of pituitary or other neoplasia during therapy [262728].

Drug interactions

Tesamorelin 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. Glucocorticoid replacement requirements may need adjustment in patients receiving concomitant glucocorticoids, given GH-axis interactions with the hypothalamic-pituitary-adrenal axis. 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.

Cytochrome P450 substrates with a narrow therapeutic index may warrant monitoring after tesamorelin initiation in theory, as GH-axis activation can modestly modulate hepatic CYP expression; clinically meaningful interactions of this kind have not been characterized in the published trial program. Concomitant use with corticosteroids may decrease therapeutic response to tesamorelin [262728].

Adverse events

Across the pivotal phase 3 program [132], the most common adverse events with tesamorelin versus placebo were injection-site reactions (erythema, pruritus, pain, irritation, hematoma, urticaria, rash at site), arthralgia, peripheral edema, paresthesia, hypoesthesia, myalgia, nausea, vomiting, fatigue, headache, and dyspepsia. 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 in post-marketing surveillance.

IGF-1 elevation is an expected pharmacodynamic effect and not an adverse event per se; clinically relevant elevations above the age- and sex-adjusted reference range prompted dose interruption per protocol. Small increases in fasting plasma glucose, fasting insulin, and HbA1c were observed in some participants; rare progression to overt diabetes occurred, and glucose intolerance is a labeled concern across all three approved products [262728]. Anti-tesamorelin antibodies were detected in approximately 50% of patients by 26 weeks; antibody formation did not consistently predict loss of efficacy in pooled analyses but contributed to between-patient variability in IGF-1 response and visceral fat reduction. Liver enzyme effects were typically favorable in HIV-associated NAFLD populations [1613].

Monitoring Tesamorelin Therapy

Baseline assessment should include a focused history for hypothalamic-pituitary axis disruption, current or prior malignancy, pituitary tumor, diabetes mellitus or glucose intolerance, pancreatitis, hypersensitivity, and pregnancy status. Baseline laboratory should include IGF-1, fasting plasma glucose and HbA1c, and routine metabolic panel. The labeled population in HIV-associated lipodystrophy will additionally have antiretroviral therapy history, viral load, CD4 count, and lipid panel documented.

On therapy: IGF-1 at baseline and periodically with dose interruption if levels exceed 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 (visceral adipose tissue or trunk fat circumference) at approximately 26 weeks and thereafter at clinically appropriate intervals. Patients should be educated to recognize and report symptoms of hypersensitivity, pancreatitis, hyperglycemia, and any new neurologic or visual symptoms that might suggest pituitary pathology [fda_label_egrifta; fda_label_egrifta_sv; fda_label_egrifta_wr].

Tesamorelin in Special Populations

Tesamorelin Evidence Quality

Evidence supporting the FDA-approved Egrifta, Egrifta SV, and Egrifta WR products for HIV-associated abdominal lipodystrophy is robust within its narrow indication [fda_essentially_a_copy]. Two pivotal phase 3 randomized double-blind placebo-controlled trials [falutz2007, falutz2010_jaids] totaling more than 800 adults demonstrated approximately 15-18% reduction in visceral adipose tissue by CT at 26 weeks, with a long-term extension publication characterizing safety and durability through 52 weeks [falutz2008] and a companion publication characterizing IGF-1 and metabolic profile [falutz2010_jcem]. Pooled analyses [stanley2012] characterized predictors of response and the relationship between visceral fat reduction and metabolic outcomes (triglycerides, adiponectin, inflammatory markers

[stanley2011_aids]). Mechanistic and pharmacology studies in healthy adults [stanley2011, makimura2011] characterized the pulsatile GH response.

Evidence in HIV-associated NAFLD is also strong, with two randomized trials [stanley2014, stanley2019] demonstrating significant reductions in hepatic fat by proton magnetic resonance spectroscopy and a lower rate of fibrosis progression at 12 months in the phase 3 Lancet HIV trial [fda_essentially_a_copy]. Translational evidence [fourman2020, stanley2021_cid, braun2017] characterizes tesamorelin-responsive hepatic transcriptomic and circulating inflammatory and metabolic signatures. Cognitive aging studies [baker2012, friedman2013] provide mechanistic evidence for GHRH-analog effects on executive function and brain neurochemistry but do not establish a cognitive indication. Phase 2 evaluation in type 2 diabetes [clemmons2017] demonstrated tolerability and visceral adipose tissue reduction without a clinically meaningful glycemic worsening signal.

Evidence specifically supporting compounded tesamorelin preparations is absent, there is no parallel efficacy program for compounded tesamorelin. Compounded use under 503A is justified only by patient-specific clinical factors that the manufactured Egrifta, Egrifta SV, or Egrifta WR product cannot accommodate [fda_essentially_a_copy]. The published phase 3 evidence base was generated with manufactured product and does not transfer to compounded preparations without separate stability, potency, and tolerability evaluation. Use for indications outside HIV-associated lipodystrophy (body composition, anti-aging, athletic performance) is outside the FDA-approved labeling and outside the published efficacy program.

Major Tesamorelin Clinical Studies

Study	Design	Participants	Duration	Finding
Falutz et al. (2007, NEJM), Pivotal phase 3 in HIV-associated lipodystrophy	Phase 3 randomized, double-blind, placebo-controlled trial of tesamorelin 2 mg subcutaneously daily versus placebo in HIV-infected adults with abdominal fat accumulation	412	26 weeks	Visceral adipose tissue by CT decreased 15.2% with tesamorelin versus a 5.0% increase on placebo; reductions in trunk fat, waist circumference, and triglycerides with expected rise in IGF-1 [falutz2007]
Falutz et al. (2008, AIDS), Long-term safety extension	52-week extension of the pivotal phase 3 trial characterizing long-term safety and durability of effect	—	52 weeks	Continued visceral fat reduction in patients maintained on tesamorelin; regain of visceral fat in patients switched to placebo, supporting the requirement

Study	Design	Participants	Duration	Finding
				for continued therapy to maintain effect [falutz2008]
Falutz et al. (2010, JAIDS), Second pivotal phase 3 plus safety extension	Phase 3 randomized, double-blind, placebo-controlled trial of tesamorelin 2 mg daily versus placebo in HIV-infected adults with abdominal fat accumulation, with 26-week safety extension	404	26 weeks primary + 26-week extension	Visceral adipose tissue decreased approximately 18% on tesamorelin versus a small increase on placebo; improvements in trunk-to-limb fat ratio and waist circumference, with favorable lipid changes and an acceptable safety profile [falutz2010_jaids]
Falutz et al. (2010, JCEM), Phase 3 IGF-1 and metabolic profile companion	Companion analysis from the phase 3 development program characterizing IGF-1 dynamics and metabolic profile	—	26-52 weeks	Dose-dependent IGF-1 rise to a new steady state within 2 weeks; relationships between IGF-1 exposure, visceral fat response, and metabolic markers [falutz2010_jcem]
Stanley et al. (2011, JCEM), Pulsatile GH and insulin sensitivity in healthy men	Randomized, placebo-controlled mechanistic trial in healthy older men with overnight frequent venous sampling and FSIVGTT for insulin sensitivity	—	Acute and 2-week dosing	Tesamorelin restored pulsatile GH secretion to a pattern resembling younger adults and improved insulin sensitivity; established the mechanistic distinction from continuous exogenous GH [stanley2011]
Makimura et al. (2011, Growth Horm IGF Res), Adiponectin and GH pulse parameters	Mechanistic substudy characterizing the relationship of adiponectin to endogenous GH pulse parameters in response to GHRH-analog stimulation	—	—	Adiponectin associated with endogenous GH pulse parameters; supports adipocyte-somatotrope axis crosstalk in the mechanism of action [makimura2011]
Stanley et al. (2011, AIDS), Inflammatory markers in HIV lipodystrophy	Analysis of inflammatory markers in the phase 3 development program in HIV-infected adults with excess abdominal fat	—	—	Reductions in inflammatory markers associated with the magnitude of visceral adipose tissue reduction on tesamorelin [stanley2011_aids]

Study	Design	Participants	Duration	Finding
Stanley et al. (2012, Clin Infect Dis), Pooled phase 3 metabolic profile	Pooled analysis across the phase 3 development program in HIV-associated lipodystrophy	—	—	Reduction in visceral adiposity associated with improved metabolic profile including triglycerides and adiponectin in HIV-infected patients receiving tesamorelin [stanley2012]
Baker et al. (2012, Arch Neurol), Tesamorelin and cognitive function in MCI and healthy aging	Phase 2 randomized, double-blind, placebo-controlled trial of tesamorelin 1 mg subcutaneously daily versus placebo in older adults with amnestic mild cognitive impairment (n=87) and cognitively intact older adults (n=65)	152	20 weeks	Improvements in executive function on tesamorelin in both MCI and cognitively intact older adults; mechanistic only, does not establish tesamorelin as a treatment for cognitive disorders [baker2012]
Friedman et al. (2013, JAMA Neurol), Brain neurochemistry MR spectroscopy substudy	Magnetic resonance spectroscopy substudy of the Baker (2012) trial measuring brain GABA, N-acetylaspartate, and myo-inositol in MCI and healthy older adults	—	—	Increases in brain GABA and changes in N-acetylaspartate and myo-inositol consistent with neuroprotective effects of GHRH-analog stimulation; mechanistic and does not establish a cognitive indication [friedman2013]
Stanley et al. (2014, JAMA), Visceral fat and liver fat in HIV-associated NAFLD	Randomized, double-blind, placebo-controlled trial of tesamorelin 2 mg subcutaneously daily versus placebo in HIV-infected adults with abdominal fat accumulation and hepatic steatosis; proton magnetic resonance spectroscopy for hepatic fat	50	6 months	Hepatic fat content by proton MR spectroscopy decreased relatively by approximately one-third on tesamorelin versus a small increase on placebo, with parallel visceral fat reduction [stanley2014]
Clemmons et al. (2017, PLoS One),	Phase 2 randomized, double-blind, placebo-controlled trial of	—	12 months	Reductions in visceral adipose tissue and triglycerides without clinically meaningful

Study	Design	Participants	Duration	Finding
Tesamorelin in type 2 diabetes	tesamorelin in adults with type 2 diabetes			changes in HbA1c or fasting glucose; established tolerability in a non-HIV population but did not lead to indication expansion [clemmons2017]
Adrian et al. (2017, AIDS), Liver enzymes and visceral fat reduction	Analysis of liver enzyme changes in relation to tesamorelin-induced visceral fat reduction in HIV-infected adults	—	—	Visceral fat reduction with tesamorelin associated with improvements in liver enzymes, consistent with subsequent NAFLD trial findings [adrian2017]
Braun et al. (2017, Growth Horm IGF Res), FGF21 and liver fat reduction	Substudy of FGF21 dynamics in adults treated with tesamorelin for HIV-associated NAFLD	—	—	Fibroblast growth factor 21 decreased after tesamorelin-induced liver fat reduction, characterizing a metabolic biomarker of hepatic response [braun2017]
Stanley et al. (2019, Lancet HIV), Phase 3 NAFLD trial	Randomized, double-blind, placebo-controlled, multicentre phase 3 trial of tesamorelin 2 mg subcutaneously daily versus placebo in adults with HIV-associated NAFLD	61	12 months	Absolute reduction in hepatic fat fraction of approximately -4.1% on tesamorelin versus +0.9% on placebo at 12 months; lower rate of fibrosis progression on tesamorelin [stanley2019]
Fourman et al. (2019, J Frailty Aging), Muscle composition	Substudy of muscle composition in HIV-infected adults treated with tesamorelin	—	—	Tesamorelin decreased intramuscular adipose tissue and increased muscle cross-sectional area [fourman2019]
Fourman et al. (2020, JCI Insight), Hepatic transcriptomic signatures	Translational substudy of the Lancet HIV phase 3 NAFLD trial using hepatic transcriptomics in pre- and post-treatment liver biopsies	—	—	Tesamorelin reduced expression of fibrosis-associated transcripts and modulated immune and metabolic pathways in HIV-associated NAFLD [fourman2020]
		—	—	

Study	Design	Participants	Duration	Finding
Lake et al. (2021, AIDS), Fat quality independent of fat quantity	Analysis of fat quality and quantity in adults treated with tesamorelin for HIV-associated lipodystrophy			Tesamorelin improved fat quality (CT attenuation and DXA-based metrics) independent of changes in fat quantity, supporting a structural as well as quantitative effect on adipose tissue [lake2021]
Russo et al. (2024, AIDS), Tesamorelin on integrase inhibitors	Population-specific evaluation of tesamorelin efficacy and safety in HIV-infected adults on integrase strand transfer inhibitor regimens	—	—	Efficacy and safety of tesamorelin maintained in adults on contemporary integrase inhibitor-based antiretroviral therapy [russo2024]
Ellis et al. (2025, J Infect Dis), Neurocognitive performance	Randomized trial of tesamorelin effects on neurocognitive performance in adults with HIV and abdominal obesity	—	—	Reported effects on neurocognitive performance metrics in adults with HIV and abdominal obesity; tesamorelin remains not FDA-approved for cognitive indications [ellis2025]

Tesamorelin Pharmacokinetics & Pharmacodynamics

Pharmacokinetics

Tesamorelin is a 44-amino-acid GHRH (1-44) analog with an N-terminal trans-3-hexenoyl modification that confers resistance to DPP-IV cleavage [fda_label_egrifta]. After subcutaneous administration of the 2 mg labeled dose, plasma concentrations are quantifiable within 15 minutes, with peak plasma concentrations typically reached within approximately 15-30 minutes and a terminal half-life on the order of 26-38 minutes. Despite the short peptide half-life, the pharmacodynamic effect, pulsatile endogenous GH secretion, produces a sustained downstream rise in serum IGF-1 to a new steady state typically within 2 weeks of daily dosing [stanley2011, falutz2010_jcem].

Population pharmacokinetic analyses in HIV-infected adults and healthy subjects [popPK studies cited in the manufactured-product labels] identified body weight as the principal covariate on apparent clearance, without clinically relevant effects of age, sex, race, renal function, or hepatic function within the studied ranges. Tesamorelin is cleared by proteolytic catabolism; cytochrome P450 enzymes are not implicated. The

2024 Egrifta WR formulation extends dosing to once weekly through a depot formulation supporting sustained subcutaneous exposure [fda_label_egrifta].

Compounded tesamorelin preparations may differ from the manufactured Egrifta SV or Egrifta WR products in lyophilization conditions, excipient profile, reconstitution diluent, and container closure; PK characteristics published for the manufactured products should not be assumed to translate without local stability and potency data [fda_label_egrifta; fda_label_egrifta_sv; fda_label_egrifta_wr].

Pharmacodynamics

Pharmacodynamic effects include stimulation of pulsatile endogenous GH secretion at the pituitary somatotrope, a downstream rise in serum IGF-1 to a new steady state within approximately 2 weeks, and tissue effects mediated through the GH-IGF-1 axis including preferential lipolysis in visceral adipose tissue. With chronic dosing, body composition changes accrue over weeks to months, with measurable reductions in visceral adipose tissue by CT detectable by 13 weeks and a plateau by 26 weeks in the pivotal trials [falutz2007, falutz2010_jaids].

Reductions in hepatic fat by proton magnetic resonance spectroscopy are observable by 6 months in HIV-associated NAFLD [stanley2014] with continued reduction through 12 months in the phase 3 NAFLD trial [stanley2019]. Fat quality measures (CT attenuation, MR-based fat composition) improve independent of fat quantity changes [lake2021]. The IGF-1 elevation is dose-dependent and is the principal labeled biomarker for monitoring.

↓↑ Comparing Tesamorelin Formulations

Three FDA-approved manufactured products share the labeled indication for HIV-associated abdominal lipodystrophy: Egrifta (original 2010 daily product), Egrifta SV (2019 reformulated daily product with a four-week post-reconstitution stability window), and Egrifta WR (2024 once-weekly subcutaneous product). The drug substance is tesamorelin acetate in each. Egrifta SV simplifies patient handling relative to the original product by extending reconstituted product stability under refrigeration [fda_label_egrifta]. Egrifta WR reduces injection burden from daily to weekly.

Compounded sterile lyophilized preparations vary in excipient profile, lyophilization conditions, and container closure. They are not bioequivalent to Egrifta, Egrifta SV, or Egrifta WR; clinicians should anticipate that local PK and tolerability may differ from manufactured-product published data and re-evaluate IGF-1 response and tolerability when switching [fda_label_egrifta_sv; fda_label_egrifta_wr].

🌡 Tesamorelin Storage and Handling

Manufactured Egrifta SV lyophilized powder is stored refrigerated at 2-8 degrees C prior to reconstitution; after reconstitution with sterile water for injection, the product is stable for up to four weeks under

refrigeration. Egrifta WR is stored per current labeling for the lyophilized product and reconstituted product. Patients should be instructed on cold-chain handling, reconstitution procedure, and recognition of temperature excursions warranting pharmacist consultation.

Compounded sterile injectable tesamorelin is stored per the pharmacy's stability data and beyond-use date assignment under USP General Chapter <797> [fda_label_egrifta_sv; fda_label_egrifta_wr; usp_797]. Refrigerated storage is typical; the beyond-use date is shorter than the manufactured product's labeled stability unless documented stability data support an extension.

Tesamorelin Compounding & Operations

503A compounding

Compounded tesamorelin 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.

Tesamorelin is FDA-approved as Egrifta, Egrifta SV, and Egrifta WR for HIV-associated abdominal lipodystrophy only. Per FDA's guidance on compounded drug products that are essentially copies of approved drug products [fda_essentially_a_copy], compounding of a 503A preparation of an FDA-approved drug is restricted unless the prescriber documents a patient-specific clinical need that the manufactured product cannot meet [fda503a]. RonanRx applies a strict review threshold for tesamorelin: compounding is restricted to documented HIV-associated lipodystrophy or a comparable medical need with a documented reason the manufactured product cannot be used (excipient sensitivity, dose individualization, or documented supply interruption). RonanRx does not compound tesamorelin for off-label use including anti-aging, general body composition in adults without HIV, or athletic performance.

Pharmacist review

Each prescription for compounded tesamorelin undergoes pharmacist review prior to dispensing. The review confirms: a documented patient-specific clinical reason that the manufactured Egrifta, Egrifta SV, or Egrifta WR product is not appropriate (excipient sensitivity, dose individualization outside the manufactured strength, documented supply interruption, or a comparable medical need); the prescribed indication falls within HIV-associated lipodystrophy or a documented clinical context with an evidence-based rationale; absence of contraindications (active malignancy, hypothalamic-pituitary axis disruption, pituitary tumor, hypersensitivity to tesamorelin or mannitol, pregnancy) [fda_label_egrifta, fda_label_egrifta_sv, fda_label_egrifta_wr]; documented baseline IGF-1 with a plan for periodic

monitoring; documented baseline glycemic status given the labeled glucose intolerance signal; and a prescribed regimen consistent with FDA labeling unless the prescriber documents a patient-specific reason for variance.

RonanRx does not fill prescriptions for compounded tesamorelin that read as routine substitution for the manufactured products without documented clinical rationale, consistent with FDA's essentially-a-copy guidance [fda_essentially_a_copy]. RonanRx does not compound tesamorelin for anti-aging, general body composition in adults without HIV, athletic performance, or other off-label indications outside the published efficacy program.

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 tesamorelin is a cold-chain product. Refrigerated transport is used between the compounding pharmacy and the patient with temperature monitoring through the shipment. 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. Manufactured Egrifta SV and Egrifta WR follow the same refrigerated-storage convention per their labels [fda_label_egrifta_sv; fda_label_egrifta_wr].

Frequently Asked Questions About Tesamorelin

Is compounded tesamorelin the same as Egrifta or Egrifta WR?

No. Egrifta, Egrifta SV, and Egrifta WR are the FDA-approved manufactured tesamorelin products [fda_label_egrifta; fda_label_egrifta_sv; fda_label_egrifta_wr]. Compounded tesamorelin is pharmacy-prepared on a patient-specific prescription and is not bioequivalent to the manufactured products. Compounded drugs are not FDA-approved [fda503a].

What is tesamorelin FDA-approved for?

Tesamorelin is FDA-approved only for the reduction of excess abdominal fat in HIV-infected adults with lipodystrophy. The three approved products are Egrifta (2010), Egrifta SV (2019 reformulation), and Egrifta WR (2024 once-weekly reformulation) [fda_label_egrifta; fda_label_egrifta_sv; fda_label_egrifta_wr]. It is not FDA-approved for weight loss, anti-aging, athletic performance, or general body composition.

How well does tesamorelin work?

In the two pivotal phase 3 trials [falutz2007, falutz2010_jaids] in HIV-infected adults with abdominal fat accumulation, tesamorelin 2 mg daily reduced visceral adipose tissue by approximately 15-18% at 26 weeks versus minimal change on placebo. Visceral fat re-accumulates after discontinuation. In HIV-associated NAFLD [stanley2014, stanley2019], tesamorelin reduces hepatic fat content and is associated with a lower rate of fibrosis progression.

When would RonanRx compound tesamorelin?

Only when the prescriber documents a patient-specific clinical need that the manufactured Egrifta, Egrifta SV, or Egrifta WR product cannot meet, for example, sensitivity to a component of the manufactured formulation, a strength or concentration not commercially available that is medically necessary, or a documented supply interruption. RonanRx does not compound tesamorelin for off-label indications including anti-aging, body composition in adults without HIV, or athletic performance [fda_essentially_a_copy; fda503a].

What are the most common side effects?

Injection-site reactions, arthralgia, peripheral edema, paresthesia, hypoesthesia, myalgia, and a dose-dependent rise in IGF-1 are the most common adverse events. Hypersensitivity reactions including rare anaphylaxis have been reported [fda_label_egrifta_wr]. Glucose intolerance is a labeled concern with small increases in fasting glucose and HbA1c in some patients [falutz2007; falutz2010_jaids; fda_label_egrifta_sv].

Who should not take tesamorelin?

Tesamorelin is contraindicated in patients with hypothalamic-pituitary axis disruption (hypophysectomy, hypopituitarism, pituitary tumor or surgery, head irradiation, head trauma), active malignancy, hypersensitivity to tesamorelin or mannitol, and pregnancy [fda_label_egrifta; fda_label_egrifta_sv; fda_label_egrifta_wr]. Caution applies in diabetes mellitus and pancreatitis history.

Does tesamorelin affect cognition?

A single phase 2 trial [baker2012] in 152 older adults (with and without mild cognitive impairment) reported improvements in executive function over 20 weeks, and a magnetic resonance spectroscopy substudy [friedman2013] documented changes in brain GABA and other metabolites. These are mechanistic findings and do not establish tesamorelin as a treatment for cognitive disorders. Tesamorelin is not FDA-approved for any cognitive indication.

Does RonanRx sell compounded tesamorelin directly to patients?

No. Compounded tesamorelin requires a patient-specific prescription written by a licensed doctor for an identified patient with a documented clinical reason that the manufactured Egrifta, Egrifta SV, or Egrifta

WR product is not appropriate, plus pharmacist review before dispensing [fda_essentially_a_copy]. RonanRx is not a direct-to-consumer storefront and does not dispense tesamorelin for off-label use [fda503a].

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How to Access Tesamorelin

Compounded Tesamorelin 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 Tesamorelin, 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)