

Tesamorelin — Research Summary

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1. What It Is

Tesamorelin is a synthetic analog of growth hormone-releasing factor (GHRF/GHRH) — a hypothalamic peptide that stimulates pituitary production and release of endogenous growth hormone. Unlike most compounds in this set, tesamorelin IS an FDA-approved prescription drug (brand name Egrifta, later EGRIFTA SV and EGRIFTA WR), administered by once-daily subcutaneous injection.

Approved indication: reduction of excess visceral abdominal fat in HIV-infected adults with lipodystrophy — a narrow, specific indication, not a general weight-loss or anti-aging approval.

2. Reported Effects in Research Literature

Tesamorelin has an unusually well-documented human clinical trial history for this reference set, since it underwent the full FDA approval pathway.

- FDA approval basis: The FDA approved tesamorelin in November 2010 based on 2 Phase 3 clinical trials involving 816 HIV-infected adults with lipodystrophy and excess abdominal fat, both showing significantly greater reductions in visceral adipose tissue (VAT, measured by CT scan) versus placebo.
- Pivotal trial (NEJM, 2007): A randomized trial (275 tesamorelin, 137 placebo) found significant reductions in visceral adipose tissue with tesamorelin; the trial was statistically powered around an 8% between-group difference in percent VAT change.
- A second placebo-controlled trial with a safety extension (Falutz et al., 2010) confirmed VAT reduction and evaluated long-term safety.
- Both pivotal trials had 26-week extension phases confirming maintenance of VAT improvements without adverse impact on blood glucose or lipid parameters over 26–52 weeks total treatment.
- Safety: Reported adverse reactions include arthralgia, injection site reactions, pain in extremities, and peripheral edema; because tesamorelin induces endogenous GH release, it should not be used in patients with active or recurrent malignancy.
- Limitation noted by the FDA at approval: because the regulatory study design required treatment discontinuation at 52 weeks, only 52-week safety data existed at approval; longer-term safety and cardiovascular-risk data were required as a post-approval condition.
- A newer F8 formulation (EGRIFTA WR, approved 2025) offers weekly reconstitution and reduced injection volume versus the original daily formulation, while maintaining bioequivalence.

3. Clinical & Preclinical Study References

Falutz J, Allas S, Blot K, et al. "Metabolic Effects of a Growth Hormone-Releasing Factor in Patients with HIV." *N Engl J Med.* 2007;357(23):2359-70. PMID: 18057338

Falutz J, Potvin D, Mamputu JC, et al. "Effects of tesamorelin, a growth hormone-releasing factor, in HIV-infected patients with abdominal fat accumulation: a randomized placebo-controlled trial with a safety extension." *J Acquir Immune Defic Syndr.* 2010;53(3):311-22. PMID: 20101189

Spooner LM, Olin JL. "Tesamorelin: a growth hormone-releasing factor analogue for HIV-associated lipodystrophy." *Ann Pharmacother.* 2012;46(2):240-7. PMID: 22298602

Dhillon S. "Tesamorelin: a review of its use in the management of HIV-associated lipodystrophy." *Drugs.* 2011;71(8):1071-91. PMID: 21668043

Regulatory/Safety Note: Tesamorelin is FDA-approved by prescription (Egrifta/EGRIFTA SV/EGRIFTA WR) for a single narrow indication (HIV-associated lipodystrophy). Non-prescription/research-labeled tesamorelin is a distinct regulatory category from the approved product and is not covered by that approval for any other use.

This compound has not been evaluated by the FDA and is not intended to diagnose, treat, cure, or prevent any disease in humans or animals.
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