EGRIFTA SV®
tesamorelin for injection

The **ONLY** FDA-approved treatment for reducing excess abdominal fat in HIV-infected patients with lipodystrophy[1]

There is more to treating people with HIV than viral suppression

REDUCE THE IMPACT OF CENTRAL ADIPOSITY

Hear how *EGRIFTA SV*® could help a patient like Tim

FDA = Food and Drug Administration; HIV = human immunodeficiency virus.

IMPORTANT SAFETY INFORMATION

Indication

EGRIFTA SV® is indicated for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy.

Limitations of Use:

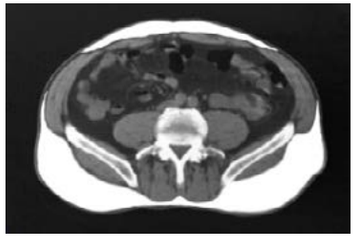
- The impact and safety of *EGRIFTA SV*® on cardiovascular health have not been studied.
- *EGRIFTA SV*® is not indicated for weight loss management.
- It is not known whether taking *EGRIFTA SV*® helps improve compliance with anti-retroviral medications.

Understanding and identifying central adiposity in HIV

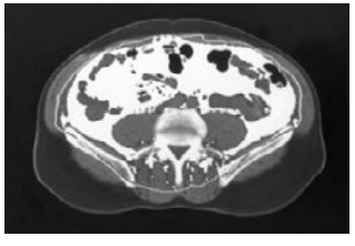
People with HIV (PWHIV) have an increased risk in developing excess visceral abdominal fat.[2]

- Excess visceral abdominal fat is the abnormal accumulation of visceral fat in the abdominal cavity and is present around internal organs.[3]
- The pathogenesis of excess visceral abdominal fat in PWHIV appears to be multifactorial, including contributions from:[3]
  - Antiretroviral therapy (ART)
  - HIV infection itself
  - Growth hormone (GH) deficiency[4]

The location of fat matters: Comparing subcutaneous fat vs. visceral abdominal fat



Subcutaneous fat



Visceral abdominal fat

Identify excess visceral abdominal fat with 3 simple steps[3]

1 **Palpate** the midsection for firmness or rigidity

2 **Measure** waist and hip circumferences

3 **Calculate** waist-to-hip ratio†

Indicators for excess visceral abdominal fat:[3†‡]

	♂	♀
Waist circumference:	≥37.4 in (95 cm)	≥37 in (94 cm)
Waist-to-hip ratio:	≥0.94	≥0.88

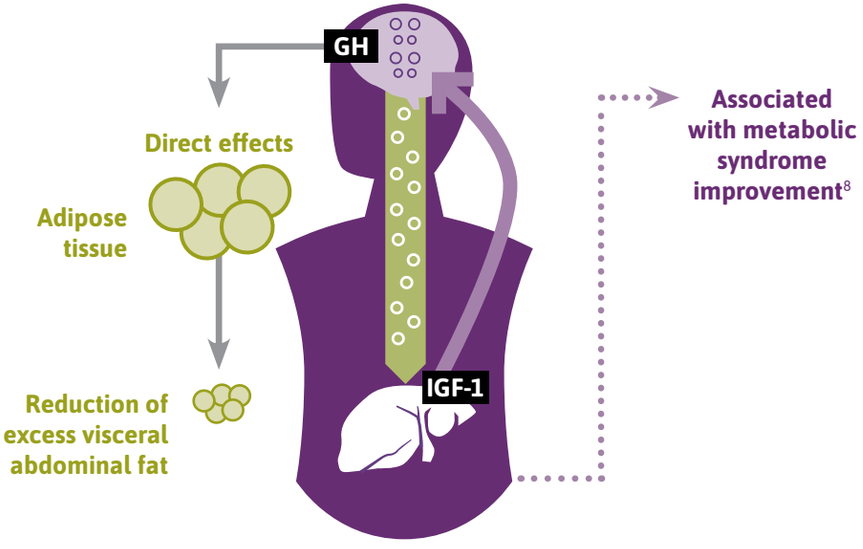
BMI and WC are independently associated with excess visceral abdominal fat.[5,6]

WC = waist circumference.
† Waist-to-hip ratio = waist circumference/hip circumference.
‡ Reference values are based on inclusion criteria in clinical trials.

EGRIFTA SV®: A unique mechanism of action that helps break down excess visceral abdominal fat in PWHIV[1]

GH deficiency has been observed in PWHIV.[7]

EGRIFTA SV® is an analog of GHRH that stimulates the body to secrete its own GH in a pulsatile manner, resulting in both anabolic and lipolytic effects.[1]



The solution to excess visceral abdominal fat may not be diet and exercise alone.

GH = growth hormone; GHRH = growth hormone-releasing hormone.

IMPORTANT SAFETY INFORMATION

Contraindications:

Do not use *EGRIFTA SV*® if patient:

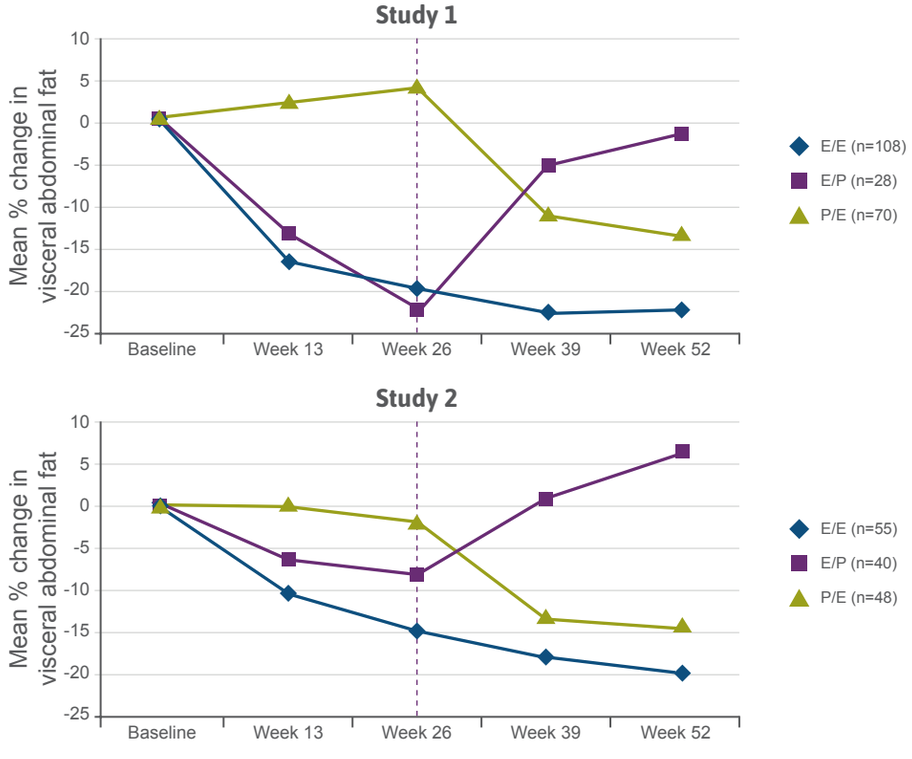
- Has a pituitary gland tumor, has had pituitary gland surgery, has other problems related to their pituitary gland, or has had radiation treatment to their head or a head injury.
- Has active cancer.
- Is allergic to tesamorelin or any of the ingredients in *EGRIFTA SV*®.
- Is pregnant or planning to become pregnant.

In two multicenter, randomized, double-blind, placebo-controlled clinical trials:

Patients who received *EGRIFTA*® experienced a significant reduction in excess visceral abdominal fat[1†‡]

Main Phase 26 weeks — **16%** — **Average reduction in excess visceral abdominal fat[†‡]** — **Extension Phase** 52 weeks — **18%**

An expert panel in agreement with the FDA determined that a **≥8% decrease in excess visceral abdominal fat was clinically significant.**[9]



E = *EGRIFTA*; P = placebo. First letter refers to Main Phase, second letter refers to Extension Phase.

In a post-hoc responder analysis[†‡] of data from two multicenter, randomized, double-blind, placebo-controlled clinical trials:

EGRIFTA® responders experienced a significant reduction in excess visceral abdominal fat and waist circumference at 26 weeks that was maintained for up to 52 weeks[†]

Main Phase 26 weeks — **27%** — **Average reduction in excess visceral abdominal fat[†‡]** — **Extension Phase** 52 weeks — **31%**

Among responders, excess visceral abdominal fat:[10‡]

- Decreased from 187 cm^2 to 137 cm^2, approaching normal levels (<130 cm^2) by Week 26.
- Was, on average, below normal levels (mean VAT: 129 ± 48 cm^2) at Week 52.

The results of the post-hoc analysis were not part of the NDA, and therefore were not reviewed by the FDA to support the approval of *EGRIFTA*®.

The safety and effectiveness of *EGRIFTA SV*® has been established based on adequate and well-controlled studies with *EGRIFTA*® (tesamorelin for injection).

***EGRIFTA SV*® is not indicated for weight loss management.**

***EGRIFTA SV*® is not approved for use in clinical conditions other than the reduction of excess abdominal fat.**

EGRIFTA SV® *has a weight-neutral effect, and may increase lean body mass by up to 5 pounds and has no BMI requirement*[1,10]

FDA = Food and Drug Administration; NDA = New Drug Application.
† In two multicenter, randomized, placebo-controlled trials. The primary outcome for these trials was change from Week 26 to Week 52 in excess visceral abdominal fat by treatment group (*EGRIFTA*® Week 0–52 or *EGRIFTA*® Week 0–26 and placebo Week 26–52).
‡ A single-slice CT scan was used to quantify excess visceral abdominal fat.

IMPORTANT SAFETY INFORMATION

Drug Interactions

- *EGRIFTA SV*® had no significant impact on the pharmacokinetic profiles of simvastatin in healthy subjects.
- Monitor patients for potential interactions when administering *EGRIFTA SV*® in combination with other drugs known to be metabolized by CYP450 liver enzyme.
- Patients on glucocorticoids may require dosage adjustment upon initiation of *EGRIFTA SV*®.

IMPORTANT SAFETY INFORMATION

Use in Specific Populations

Lactation: Mothers should not breastfeed if they receive *EGRIFTA SV*®.
Pediatric Use: Safety and effectiveness in pediatric patients have not been established.
Geriatric Use: There is no information on the use of *EGRIFTA SV*® in patients greater than 65 years of age.
Renal and Hepatic Impairment: Use in renal and hepatic impairment has not been studied.

EGRIFTA SV® (tesamorelin for injection): Building on 10+ years of established safety†

EGRIFTA SV® is generally well tolerated

Within the Phase 3 studies, 740 PWHIV who had lipodystrophy and excess abdominal fat received *EGRIFTA*®; of these, 543 received *EGRIFTA*® during the initial 26-week placebo-controlled Main Phase studies.[1]

The most commonly reported adverse events were:[1]

- Hypersensitivity reactions (rash, urticaria)
- Edema-related reactions (e.g., arthralgia, pain in extremity, peripheral edema, and carpal tunnel syndrome)
- Hyperglycemia
- Injection-site reactions (e.g., injection site erythema, pruritus, pain, urticaria, irritation, swelling, and hemorrhage)

The safety and effectiveness of *EGRIFTA SV*® has been established based on adequate and well-controlled studies with *EGRIFTA*® (tesamorelin for injection).

***EGRIFTA*® was approved in 2010 and *EGRIFTA SV*® in 2019.**

† The safety of *EGRIFTA SV*® (2 mg/vial formulation) has been established based on clinical trials conducted with *EGRIFTA*® (1 mg/vial formulation). Adverse events for the 1.4 mg dose (2 mg/vial formulation) of *EGRIFTA SV*® are expected to be similar to those observed with the 2 mg dose (1 mg/vial formulation) of *EGRIFTA*®.

EGRIFTA SV® is a once-daily subcutaneous injection

EGRIFTA SV® dosing & administration[1]

- Once-daily dosing of 1.4 mg (small volume of only 0.35 mL reconstituted solution)
- Store at room temperature (**no refrigeration required**)
- Small needle size (1/2 30-gauge needle)

Medication box

Injection box

Available in a package of 2 boxes with a 30-day supply

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- **Increased risk of neoplasms**: Preexisting malignancy should be inactive, and its treatment complete prior to starting *EGRIFTA SV*®. *EGRIFTA SV*® should be discontinued if the patient has evidence of recurrent malignancy.
- **Elevated IGF-1**: Monitor regularly IGF-1 levels in all patients during *EGRIFTA SV*® therapy. Consider discontinuing in patients with persistent elevations (e.g., >3 SDS).
- **Fluid retention**: May include edema, arthralgia, and carpal tunnel syndrome.
- **Glucose intolerance or diabetes mellitus**: May develop with *EGRIFTA SV*® use. Evaluate glucose status prior to and during therapy with *EGRIFTA SV*®.
- **Hypersensitivity reactions**: Advise patients to seek immediate medical attention and discontinue treatment if suspected.
- **Injection-site reactions**: Advise patients to rotate injection sites to different areas of the abdomen to decrease injection-site reactions.
- **Increased mortality in patients with acute critical illness**: Consider discontinuation in critically ill patients.

Contact THERA patient support® to get your patients started with *EGRIFTA SV*® today!

Our Nurse Navigators can enhance your patients' experience and promote treatment adherence.

EGRIFTA SV®
tesamorelin for injection

The **ONLY** FDA-approved treatment for reducing excess abdominal fat in HIV-infected patients with lipodystrophy[1]

27% demonstrated reduction in excess visceral abdominal fat in responders after 26 weeks of treatment.[10]

EGRIFTA SV® (tesamorelin for injection): Building on 10+ years of established safety.[1]

EGRIFTA SV® has a weight-neutral effect, and may increase lean body mass by up to 5 pounds and has no BMI requirement.[1,10]

EGRIFTA SV® is not approved for use in clinical conditions other than the reduction of excess abdominal fat.
EGRIFTA SV® is not indicated for weight loss management.

IMPORTANT SAFETY INFORMATION

Adverse Reactions

The most commonly reported adverse reactions include injection-site reactions, arthralgia, pain in extremity, myalgia, and peripheral edema.

For complete disclosure of *EGRIFTA SV*® product information, please read the **Full Prescribing Information**, available at www.egriftasv.com.

For more information about *EGRIFTA SV*®, contact THERA patient support® toll-free at 1-833-23THERA (1-833-238-4372). To report suspected adverse reactions, contact THERA patient support® toll-free or FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

References: 1. *EGRIFTA SV*® (tesamorelin for injection) Prescribing Information. Theratechnologies Inc. October 2019. **2.** Moyle G, Moutschen M, Martínez E, *et al*. Epidemiology, assessment, and management of excess abdominal fat in persons with HIV infection. *AIDS Rev*. 2010;12(1):3-14. **3.** Lake JE, *et al*. Practical review of recognition and management of obesity and lipohypertrophy in human immunodeficiency virus infection. *Clin Infect Dis*. 2017;64(10):1422-1429. **4.** Rietschel, P, Hadigan C, Corcoran C, *et al*. Assessment of growth hormone dynamics in human immunodeficiency virus-related lipodystrophy. *J Clin Endocrinol Metabolism*. 2001;86;504-10. **5.** Janssen I, Heymsfield SB, Allison DB, Kotler DP, Ross R. Body mass index and waist circumference independently contribute to the prediction of nonabdominal, abdominal subcutaneous, and visceral fat. *Am J Clin Nutr*. 2002;75(4):683-688. **6.** Joy T, Keogh HM, Allison DB, Hadigan C, *et al*. Relationship of Body Composition to BMI in HIV-Infected Patients with Metabolic Abnormalities. *J Acquir Immune Defic Syndr*. 2008;47(2):174-84. **7.** Stanley TL, Grinspoon SK. Effects of growth hormone-releasing hormone on visceral fat, metabolic, and cardiovascular indices in human studies. *Growth Horm IGF Res*. 2015;25(2):59-65. **8.** Bedimo R, Gonzalo T, McGary CS, *et al*. Visceral fat reduction with tesamorelin associated with metabolic syndrome reversal (abstract 709). Conference on Retroviruses and Opportunistic Infections. 2023. **9.** Snyder SW. Regulatory Considerations for the Treatment of Lipodystrophy. Report of a Forum for Collaborative HIV Research Roundtable discussion. October 25, 2004; Washington DC. **10.** Stanley TL, Falutz J, Marsolais C, *et al*. Reduction in visceral adiposity is associated with an improved metabolic profile in HIV-infected patients receiving tesamorelin. *Clin Infect Dis*. 2012;54(11):1642-1651.

THERA technologies

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