



WHEN IT'S
HARD BELLY
(EXCESS VISCERAL
ABDOMINAL FAT)

IT MAY BE TIME FOR
EGRIFTA SV[®]

A different kind of fat
may need a different
kind of treatment

**FIND A SPECIALIST
AT EGRIFTASV.COM**

**IF YOU ARE LIVING WITH HIV AND LIPODYSTROPHY ASK
YOUR HEALTHCARE PROVIDER ABOUT EGRIFTA SV[®].**

Please see Important Safety Information throughout, and the enclosed full Prescribing Information, Patient Information, and Patient Instructions for Use.

These documents are also available at <http://egriftasv.com>.

EGRIFTA SV[®] is an injectable prescription medicine used to reduce excess abdominal fat in adult patients living with HIV and lipodystrophy. *EGRIFTA SV[®]* is a growth hormone-releasing factor (GHRF) analog.

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 antiretroviral medications.

*This 2 mg/vial strength of tesamorelin has the same efficacy and safety of tesamorelin 1 mg/vial. The 2 mg/vial is more concentrated than the 1 mg/vial, and the recommended daily dose is 1.4 mg.

 **EGRIFTA SV[®]**
tesamorelin for injection

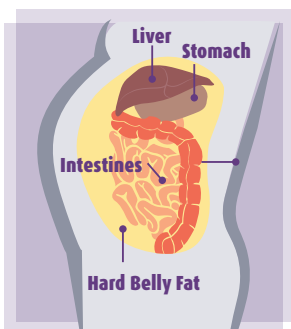
Understanding excess visceral abdominal fat (HARD BELLY) (and why it's different from regular fat)

If you are living with HIV, one issue that may be challenging is lipodystrophy. Lipodystrophy refers to changes in body fat that include buildup or loss of fat in certain areas of the body. HARD BELLY (excess visceral abdominal fat) results when the buildup of extra hard fat in the abdominal (belly) area pushes up against the abdominal wall and stretches the muscles until they become taut.

HARD BELLY fat is not like regular fat. Regular fat sits just under the skin (subcutaneous fat) and is soft and squishy or easy to pinch or move around.

HARD BELLY is found deeper and:

- Is surrounding organs
- May be associated with fat accumulation in organs
- Feels harder and firmer than regular fat
- May be hard to reduce with diet and exercise alone



HARD BELLY may be associated with:

- Serious health issues*
- A decrease in physical abilities

***EGRIFTA SV® is not approved to reduce the health consequences of excess visceral abdominal fat**

IMPORTANT SAFETY INFORMATION

What is EGRIFTA SV® (tesamorelin for injection)?

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- EGRIFTA SV® is not for weight loss management.
- The long-term safety of EGRIFTA SV® on the heart and blood vessels (cardiovascular) is not known.
- It is not known whether taking EGRIFTA SV® helps improve how well you take your antiretroviral medications.
- It is not known if EGRIFTA SV® is safe and effective in children, do not use in children.

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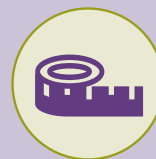
Checking for excess visceral abdominal fat (HARD BELLY)

HARD BELLY may be hard for you to accurately describe and can be mistaken for general weight gain or obesity. Talk to your healthcare provider about what you're feeling and ask them to check for HARD BELLY.

Your healthcare provider can check for excess visceral abdominal fat in a few simple ways, including:



Feeling your abdomen (belly) for hardness and firmness



Measuring your waist and hips circumference



Calculating your waist-to-hip ratio

How to measure:

Waist: Measure at the belly button. Make sure the tape is horizontal to the floor and around the waist.

Hips: Measure at the widest portion of the buttocks, making sure the tape is horizontal.

Waist-to-hip ratio = waist circumference ÷ hip circumference

Indicators of excess visceral abdominal fat*



MEN

Waist circumference

≥37.4 in (95 cm)

Waist-to-hip ratio ≥0.94



WOMEN

Waist circumference

≥37 in (94 cm)

Waist-to-hip ratio ≥0.88

*Based on inclusion criteria in clinical trials.

Have you noticed your waist circumference has gotten larger and the shape of your abdomen has changed? If so, it could be HARD BELLY. **If you have trouble managing excess visceral abdominal fat on your own with exercise and a healthy diet, ask your healthcare provider about EGRIFTA SV®.**

Helping to reduce excess visceral abdominal fat (HARD BELLY) (and maintain your results)

EGRIFTA SV[®] (tesamorelin for injection) is an FDA approved treatment* used to reduce excess visceral abdominal fat in adult patients living with HIV and lipodystrophy. *EGRIFTA SV*[®] is a prescription treatment that you inject daily subcutaneously (under the skin) around your abdominal (belly) area.

Tesamorelin for injection was studied in two clinical trials in adult patients living with HIV who developed HARD BELLY.

- Each trial lasted 6 months, with an additional 6-month extension phase.
- Patients receiving tesamorelin for injection saw significant reductions in excess visceral abdominal fat (HARD BELLY).

EGRIFTA SV[®] is not indicated for weight loss management.

Average of Trial 1

↓ 18%

REDUCTION IN EXCESS
VISCERAL ABDOMINAL FAT

Average of Trial 2

↓ 14%

REDUCTION IN EXCESS
VISCERAL ABDOMINAL FAT



Actual patient
living with HIV.

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EGRIFTA SV[®] may help reduce excess visceral abdominal fat by changing how certain hormones (chemicals that your body produces naturally) are released. To maintain any reduction in HARD BELLY, your healthcare provider may recommend that you continually use *EGRIFTA SV*[®].

Tesamorelin for injection reduced excess visceral abdominal fat



People who used tesamorelin for injection continually for 1 year maintained their results over this time period

Without tesamorelin for injection, excess visceral abdominal fat came back



Excess visceral abdominal fat returned when tesamorelin for injection was stopped after 6 months of therapy

IMPORTANT SAFETY INFORMATION

You should not take *EGRIFTA SV*[®] if you:

- Have a pituitary gland tumor, surgery, or other problems related to your pituitary gland, or have had radiation treatment to your head or head injury.
- Have active cancer.
- Are allergic to tesamorelin or any of the ingredients in *EGRIFTA SV*[®].
- Are pregnant or become pregnant. If you become pregnant, stop using *EGRIFTA SV*[®] and talk with your healthcare provider.
- Are less than 18 years of age.

Before using *EGRIFTA SV*[®], tell your healthcare provider if you:

- Have or have had cancer.
- Have problems with blood sugar or diabetes.
- Have scheduled heart or stomach surgery.
- Have breathing problems.
- Are breastfeeding or plan to breastfeed.
- Are taking any other prescription and non-prescription medicines, vitamins, and herbal supplements.

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 **EGRIFTA SV**[®]
tesamorelin for injection

Talking to your healthcare team (and preparing for your conversation)

HARD BELLY (excess visceral abdominal fat) is often mistaken for weight gain or obesity. However, unlike regular fat, which is soft or doughy and sits just below the skin, the HARD BELLY fat is found around organs, mostly in your abdominal cavity. That's why it's important to let your healthcare team, including your healthcare provider, know how your belly has changed in shape or feel and how it may limit your general mobility, like bending over or difficulty breathing during physical activities. This can help your healthcare provider determine if you have HARD BELLY or other issues (like heartburn, bloating, or weight gain with regular fat).

Before you visit your healthcare provider, you should ask yourself some questions. These may help guide your conversation towards a different type of treatment for your excess visceral abdominal fat:

1. Do any of the following apply to you? Check all that apply.
 - My abdomen feels hard and/or uncomfortable
 - My waist has gotten wider over time
 - The change in the size and shape of my belly has affected the way my clothing fits
 - I cannot get rid of my excess belly fat with diet and exercise alone
 - The change in the size and shape of my belly has caused me to feel distressed or frustrated in ways that are affecting my well-being
2. Do any of these risk factors for HIV-related excess visceral abdominal fat apply to you?
 - Living with HIV _____ years _____ months
 - Taking antiretroviral therapy (ART)
3. How long have you been taking ART?
_____ years _____ months
How long after that did your belly begin feeling hard?
_____ years _____ months
4. Check any steps you have taken to try to reduce excess belly fat.
 - Changed my diet
 - Started or improved an exercise routine
 - Switched HIV therapies (as per my healthcare provider's recommendation)

5. HARD BELLY may be associated with other health issues.*
If you have been diagnosed with other medical conditions, list them below and be sure to mention them to your healthcare provider: _____

6. What are your waist circumference, hip circumference, and waist-to-hip ratio?

Waist circumference: _____ inches

Hip circumference: _____ inches

Waist-to-hip ratio: _____

How to measure:

Waist: Measure at the belly button. Make sure the tape is horizontal to the floor and around the waist.

Hips: Measure at the widest portion of the buttocks, making sure the tape is horizontal.

Waist-to-hip ratio = waist circumference ÷ hip circumference

***EGRIFTA SV[®] is not approved to reduce the health consequences of excess visceral abdominal fat.**

IMPORTANT SAFETY INFORMATION

EGRIFTA SV[®] may cause serious side effects including:

- **Increased risk of new cancer in HIV positive patients or your cancer coming back (reactivation).** Stop using EGRIFTA SV[®] if any cancer symptoms come back.
- **Increased levels of your insulin-like growth factor-1 (IGF-1).** Your healthcare provider will do blood tests to check your IGF-1 levels while you are taking EGRIFTA SV[®].
- **Serious allergic reaction** such as rash or hives anywhere over the body or on the skin, swelling of the face or throat, shortness of breath or trouble breathing, fast heartbeat feeling of faintness or fainting, itching and reddening or flushing of the skin. **If you have any of these symptoms, stop using EGRIFTA SV[®] and get emergency medical help right away.**
- **Swelling or fluid retention.** Call your healthcare provider if you have swelling, an increase in joint pain, or pain or numbness in your hands or wrist.
- **Increase in blood sugar (glucose) or diabetes.**
- **Injection site reactions.** Injection site reactions are a common side effect of EGRIFTA SV[®], but may sometimes be serious.
- **Increased risk of death in people who have critical illness because of heart or stomach surgery, trauma or serious breathing (respiratory) problems** has happened when taking certain growth hormones.

Access and assistance throughout treatment

Expert Patient Care Coordinators are standing by to help you:



- Enroll in the *EGRIFTA SV*[®] Co-Pay Assistance Program
- Identify the best insurance and coverage options
- Follow up about your insurance benefits
- Find specialty pharmacies in your insurance network, so you can quickly receive your medication
- Prepare for therapy
- Verify eligibility to enroll in the *EGRIFTA SV*[®] Financial Assistance Program, which may help with the cost of therapy

THERA patient support[®]

Our THERA patient support[®] Staff Nurses are ready to help:



- Train on proper injection and reconstitution techniques, either on the phone or at home
- Share advice for starting and staying on therapy
- Answer common therapy-related questions throughout your treatment

Expert assistance – just a phone call away

Call THERA patient support[®] toll-free at

1-833-23THERA (1-833-238-4372)

Monday-Friday, 8:30 a.m. - 8 p.m. ET

Voice mail messages will be returned within the next business day.

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How do I store *EGRIFTA SV*[®]?

- You will be given two boxes from the pharmacy when you get your prescription of *EGRIFTA SV*[®]:
 - Store the 2 mg *EGRIFTA SV*[®] vials in the Medication Box they come in, at room temperature between 68°F to 77°F (20°C to 25°C).
 - Store the Sterile Water for Injection, syringes and needles that come in the Injection Box at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep *EGRIFTA SV*[®] vials out of the light.
- After mixing, use *EGRIFTA SV*[®] **right away**. Throw away any unused *EGRIFTA SV*[®] after mixing.
- **Do not** store, freeze, or refrigerate *EGRIFTA SV*[®] after it has been mixed with the Sterile Water.
- Throw away any Sterile Water for Injection left in the bottle after use.
- Do not use *EGRIFTA SV*[®] after the expiration date (EXP) printed on the carton and vial labels.

Keep *EGRIFTA SV*[®] and all medicines out of the reach of children.

General information about the safe and effective use of *EGRIFTA SV*[®]

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use *EGRIFTA SV*[®] for a condition for which it was not prescribed. Do not give *EGRIFTA SV*[®] to other people, even if they have the same symptoms you have. It may harm them.

Do not share your syringe or needles with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.

IMPORTANT SAFETY INFORMATION

The most common side effects of *EGRIFTA SV*[®] include:

- Pain in legs and arms
- Muscle pain

These are not all of the possible side effects of *EGRIFTA SV*[®]. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or to THERA patient support[®] toll-free at 1-833-23THERA (1-833-238-4372).

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 **EGRIFTA SV**[®]
tesamorelin for injection

Important Information for Patients about *EGRIFTA SV*[®] (tesamorelin for injection)

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**Don't delay.
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provider today.**

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