YOU'VE WORKED TO CONTROL YOUR HIV. NOW, TIME TO WORK ON YOUR HIV-RELATED EXCESS BELLY FAT.

In two separate clinical trials of HIV-Infected people with lipodystrophy, each lasting 6 months, EGRIFTA® (tesamorelin for injection) reduced HIV-related excess belly fat by an average of 18% in the first trial, and 14% in the second trial. This reduction in excess belly fat resulted in an approximate 1-inch reduction in waist size. Individual results may vary. On average, patients on EGRIFTA® did not lose weight.

Like HIV, HIV-related excess belly fat is a chronic condition. In clinical studies:
- People who used EGRIFTA® continuously for 1 year maintained their results over this time period
- People who stopped taking EGRIFTA® after 6 months had their HIV-related excess belly fat come back

EGRIFTA® is believed to work with your own body to produce natural growth hormone to reduce your excess belly fat.

**Indication:**
EGRIFTA® is a daily injectable prescription medicine to reduce the excess abdominal fat in HIV-infected patients with lipodystrophy.

**Limitations of use:**
- The impact and safety of EGRIFTA® on cardiovascular health has not been studied
- EGRIFTA® is not indicated for weight-loss management
- It's not known whether taking EGRIFTA® helps improve compliance with antiretroviral medications
- EGRIFTA® is not recommended to be used in children

**Important Risk Information**
**Do not use EGRIFTA® if you:**
- Have pituitary gland tumor, pituitary gland surgery, or other problems related to your pituitary gland
- Have active cancer (either newly diagnosed or recurrent) or are receiving treatment for cancer
- Are allergic to tesamorelin or any of the ingredients in EGRIFTA®, including mannitol or sterile water
- Are pregnant or become pregnant

**Before using EGRIFTA®, tell your healthcare provider if you:**
- Have or have had cancer
- Have diabetes
- Are breastfeeding or plan to breastfeed
- Have kidney or liver problems
- Have any other medical condition
- Take prescription or non-prescription medicines, vitamins, or herbal supplements

**EGRIFTA® may cause serious side effects, including:**
- Serious allergic reaction. Stop using EGRIFTA® and get emergency help right away if you have any of the following symptoms: rash over your body, hives, swelling of your face or throat, shortness of breath or trouble breathing, fast heartbeat, feeling of faintness or fainting
- Swelling (fluid retention). EGRIFTA® can cause swelling in some parts of your body. Call your healthcare provider if you have an increase in joint pain, or pain or numbness in your hands or wrist (carpal tunnel syndrome)
- Increase in glucose (blood sugar) intolerance and diabetes

- Injection-site reactions, such as redness, itching, pain, irritation, bleeding, rash, and swelling. Change (rotate) your injection site to help lower your risk for injection-site reactions

**The most common side effects of EGRIFTA® include:**
- Joint pain
- Pain in legs and arms
- Swelling in your legs
- Muscle soreness
- Tingling
- Numbness and pricking
- Nausea
- Vomiting
- Rash
- Itching

EGRIFTA® will NOT cure HIV or lower your chance of passing HIV to others.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see Consumer Brief Summary of EGRIFTA® on following page.

Ask your healthcare provider if EGRIFTA®, the first and only FDA-approved medicine for HIV-related excess belly fat, may be right for you. For more information, visit www.egrifta.com or call the AXIS Center at 1-877-714-AXIS (2947).
Consumer Brief Summary for EGRIFTA® (tesamorelin for injection)

EGRIFTA® (eh-GRIF-tuh) (tesamorelin for injection) for subcutaneous use

Read the Patient Information that comes with EGRIFTA® before you start to take it and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is EGRIFTA®?
- EGRIFTA® is an injectable prescription medicine to reduce the excess in abdominal fat in HIV-infected patients with lipodystrophy. EGRIFTA® contains a growth hormone-releasing factor (GRF).
- The impact and safety of EGRIFTA® on cardiovascular health has not been studied.
- EGRIFTA® is not indicated for weight-loss management.
- It is not known whether taking EGRIFTA® helps improve compliance with antiretroviral medications.
- It is not known if EGRIFTA® is safe and effective in children.

Who should not use EGRIFTA®?
Do not use EGRIFTA® if you:
- have pituitary gland tumor, pituitary gland surgery, or other problems related to your pituitary gland.
- have active cancer (either newly diagnosed or recurrent) or are receiving treatment for cancer.
- are allergic to tesamorelin or any of the ingredients in EGRIFTA®. See the end of this leaflet for a complete list of ingredients in EGRIFTA®.
- are pregnant or become pregnant. If you become pregnant, stop using EGRIFTA® and talk with your healthcare provider. See "What should I tell my healthcare provider before using EGRIFTA®?"

What should I tell my healthcare provider before using EGRIFTA®?
Before using EGRIFTA®, tell your healthcare provider if you:
- have or have had cancer.
- have diabetes.
- are breastfeeding or plan to breastfeed. It is not known if EGRIFTA® passes into your breast milk. The Centers for Disease Control and Prevention (CDC) recommends that HIV-infected mothers not breastfeed to avoid the risk of passing HIV infection to your baby.
- Talk with your healthcare provider about the best way to feed your baby if you are taking EGRIFTA®.
- have kidney or liver problems.
- have any other medical condition.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. EGRIFTA® may affect the way other medicines work, and other medicines may affect how EGRIFTA® works. Know the medicines you take. Keep a list with you to show your healthcare provider and pharmacist when you get a new medicine.

How should I use EGRIFTA®?
- Read the detailed "Instructions for Use" that comes with EGRIFTA® before you start using EGRIFTA®. Your healthcare provider will show you how to inject EGRIFTA®.
- Use EGRIFTA® exactly as prescribed by your healthcare provider.
- Inject EGRIFTA® under the skin (subcutaneously) of your stomach area (abdomen).
- Change (rotate) the injection site on your stomach area (abdomen) with each dose.
- Do not inject EGRIFTA® into scar tissue, bruises, or your navel.
- Do not share needles or syringes with other people. Sharing of needles can result in the transmission of infectious diseases, such as HIV.

What are the possible side effects of EGRIFTA®?
EGRIFTA® may cause serious side effects including:
- Serious allergic reaction. Some people taking EGRIFTA® may have an allergic reaction. Stop using EGRIFTA® and get emergency help right away if you have any of the following symptoms:
  - a rash over your body
  - hives
  - swelling of your face or throat
  - shortness of breath or trouble breathing
  - fast heartbeat
  - feeling of faintness or fainting
- Swelling (fluid retention). EGRIFTA® can cause swelling in some parts of your body. Call your healthcare provider if you have an increase in joint pain, or pain or numbness in your hands or wrist (carpal tunnel syndrome).
- Increase in glucose (blood sugar) intolerance and diabetes. Your healthcare provider will measure your blood sugar periodically.
- Injection-site reactions. Change (rotate) your injection site to help lower your risk for injection-site reactions. Call your pharmacist for medical advice if you have 3 or more symptoms around the area of the injection site:
  - redness
  - itching
  - pain
  - irritation

The most common side effects of EGRIFTA® include:
- joint pain
- pain in legs and arms
- swelling in your legs
- muscle soreness
- tingling, numbness, and pricking

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of EGRIFTA®. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. To report side effects, contact EMD Serono toll-free at 1-800-283-8088, ext. 5563. You may request side effects to the FDA at 1-800-FDA-1088.

Keep EGRIFTA® and all medicines out of the reach of children.

General information about the safe and effective use of EGRIFTA®:
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use EGRIFTA® for a condition for which it was not prescribed.

Do not give EGRIFTA® to other people, even if they have the same symptoms you have. It may harm them.

Do not share your EGRIFTA® syringe with another person, even if the needle is changed.

Do not share your EGRIFTA® needles with another person.

This Patient Information Leaflet summarizes the most important information about EGRIFTA®. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about EGRIFTA® that is written for healthcare professionals.

For more information about EGRIFTA®, go to www.EMD.com or contact the FDA toll-free at 1-888-463-6762.

What are the ingredients in EGRIFTA®?
Active ingredient: tesamorelin
Inactive ingredients: mannitol and Sterile Water for Injection