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).

EGRIFTA®
tesamorelin for injection

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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. *EGRIFTA*® is not recommended to be used 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 healthcare provider for medical advice if you have the following symptoms around the area of the injection site:
  - redness
  - itching
  - pain
  - irritation
  - bleeding
  - rash
  - swelling

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

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 report 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.*EGRIFTA*.com or contact the AXIS Center toll-free at 1-877-714-2947.

What are the ingredients in *EGRIFTA*®?

Active ingredient: tesamorelin
Inactive ingredients: mannitol and Sterile Water for Injection

EMD Serono

EMD Serono, Inc. is a subsidiary of Merck KGaA, Darmstadt, Germany

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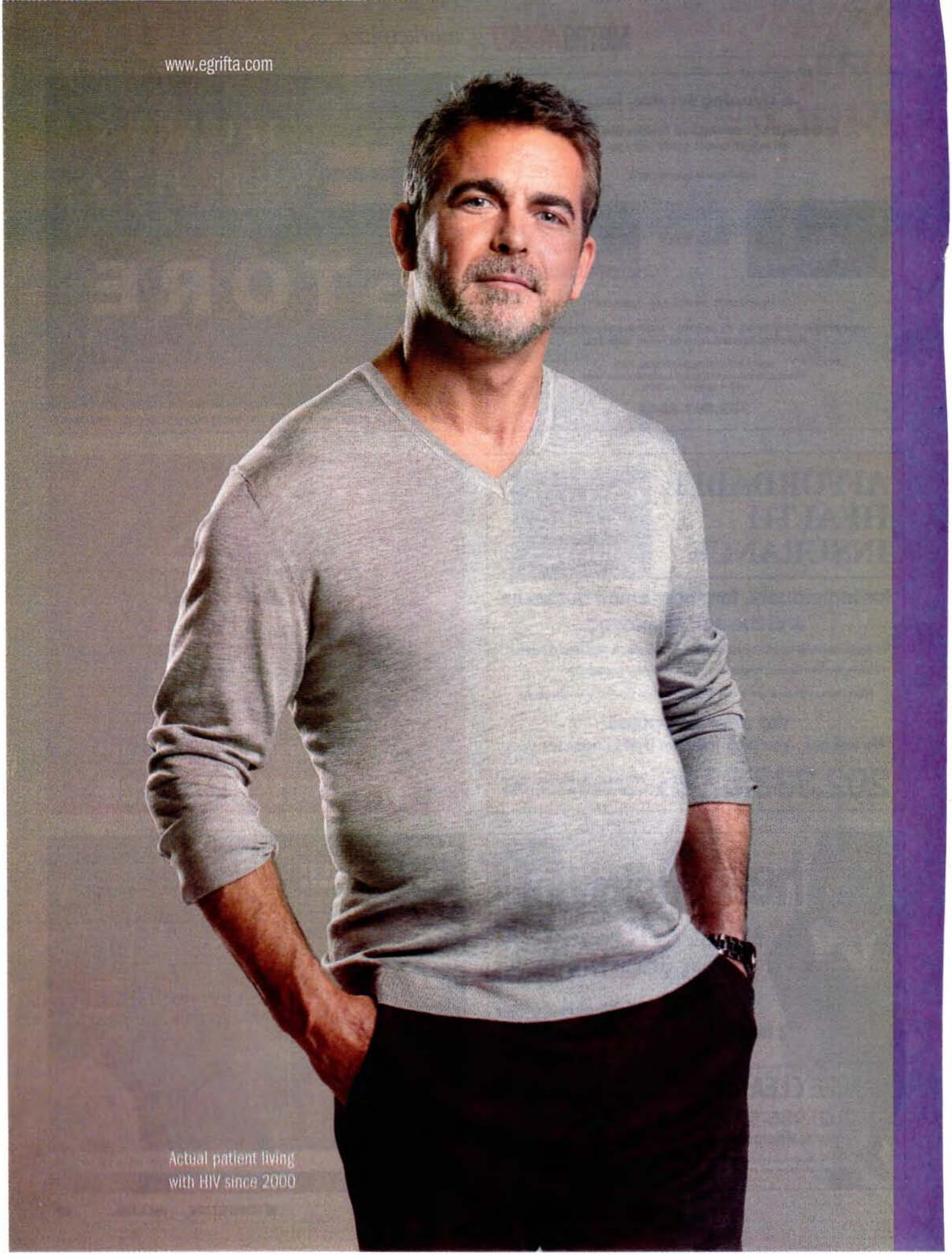
Distributed by EMD Serono, Inc., Rockland, MA 02370


www.egrifta.com
Actual patient living
with HIV since 2000