

## **Patient Information**

**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 anti-retroviral 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 non-prescription 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 doctor for medical advice about side effects. You may report side effects to FDA at 1-800- FDA-1088

You may also report side effects to  **THERA patient support**™ toll-free at 1-833-23-THERA (1-833-238-4372).

**How do I store EGRIFTA®?**

- EGRIFTA® has two boxes dispensed by the pharmacy:
  - Store the Medication Box of EGRIFTA® vials in the refrigerator between 2°C to 8°C (36°F to 46°F).

- Store the box of Sterile Water for Injection, syringes and needles at room temperature between 20°C to 25°C (68°F to 77°F).
- Keep EGRIFTA® vials in Medication Box away from light.
- Do not freeze.
- Do not use EGRIFTA® after the expiration date printed on the carton and vial labels.
- After mixing, use EGRIFTA® right away and throw away any unused EGRIFTA®. Do not store mixed EGRIFTA®. Also, throw away the used bottle of Sterile Water for Injection.

**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 or needles with another person. You may give an infection to them or get an infection from them.**

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](http://www.EGRIFTA.com) or contact  THERA patient support™ toll-free at 1-833-23-THERA (1-833-238-4372).

**What are the ingredients in EGRIFTA®?**

**Active ingredient:** tesamorelin

**Inactive ingredients:** mannitol and Sterile Water for Injection

This Patient Information has been approved by the U.S. Food and Drug Administration.

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