PATIENT INFORMATION

EGRIFTA WR™ [eh-GRIF-tuh dub-uh-yoo-ahr]
(tesamorelin) for injection
for subcutaneous use
11.6 mg/vial

Read the Patient Information that comes with EGRIFTA WR before you start to take EGRIFTA WR 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 WR?

EGRIFTA WR is a prescription medicine used to reduce the excess stomach-area (abdominal) fat in HIV-infected adult patients with lipodystrophy. EGRIFTA WR is a growth hormone-releasing factor (GHRF).

The long-term safety of EGRIFTA WR on the heart and blood vessels (cardiovascular) is not known.

EGRIFTA WR is not for weight loss management.

It is not known whether taking EGRIFTA WR helps improve how well you take (compliance with) antiretroviral medicines.

It is not known if EGRIFTA WR is safe and effective in children.

EGRIFTA WR is not recommended to be used in children with open or closed bone growth plates (epiphyses).

Who should not use EGRIFTA WR?

Do not use EGRIFTA WR if you:

- have a pituitary gland tumor, have had pituitary gland surgery, have other problems related to your pituitary gland, or have had radiation treatment to your head or a head injury.
- have active cancer. Any previous cancer should be inactive, and any previous cancer treatment should be complete before starting EGRIFTA WR.
- are allergic to tesamorelin or any of the ingredients in EGRIFTA WR. See the end of this leaflet for a complete list of ingredients in EGRIFTA WR.
- are pregnant or plan to become pregnant. EGRIFTA WR can harm your unborn baby. If you become pregnant, stop using EGRIFTA WR and talk with your healthcare provider.

What should I tell my healthcare provider before using EGRIFTA WR?

Before using EGRIFTA WR, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had cancer.
- have problems with your blood sugar or diabetes. Some people with diabetes who use EGRIFTA WR may develop or may have worsening eye problems.
- have scheduled heart or stomach surgery.
- have breathing problems.
- are breastfeeding or plan to breastfeed. It is not known if EGRIFTA WR 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 using EGRIFTA WR.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use EGRIFTA WR?

- Read the detailed Instructions for Use that comes with EGRIFTA WR before you start using it. Your healthcare provider will show you how to inject EGRIFTA WR.
- Use EGRIFTA WR exactly as your healthcare provider tells you to use it.
- Inject EGRIFTA WR under the skin (subcutaneously) of your stomach-area (abdomen).
- Change (rotate) the injection site on your stomach-area with each dose. Do not inject EGRIFTA WR into scar tissue, bruises or your belly button. There are two EGRIFTA formulations (EGRIFTA WR and EGRIFTA SV) with different recommended dosages. **EGRIFTA WR and EGRIFTA SV are not substitutable.**
- **Do not share your EGRIFTA WR 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.**

What are the possible side effects of EGRIFTA WR?

EGRIFTA WR may cause serious side effects, including:

- **increase risk of new cancer in HIV positive patients or your cancer coming back (reactivation).** Stop using EGRIFTA WR 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 WR.
- **swelling (fluid retention).** EGRIFTA WR can cause swelling in some parts of your body. Call your healthcare provider if you have swelling, an increase in joint pain or pain or numbness in your hands or wrist (carpal tunnel syndrome). Joint pain and swelling of your arms, hands, legs and feet are common side effects of EGRIFTA WR but may sometimes be serious.
- **increase in blood sugar (glucose) or diabetes.** Your healthcare provider will check your blood sugar before you start taking EGRIFTA WR and during your treatment with EGRIFTA WR.

- **serious allergic reaction.** Some people using EGRIFTA WR may have an allergic reaction. **Stop using EGRIFTA WR and get emergency medical 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
  - itching
  - reddening or flushing of the skin
- **injection site reactions.** Injection site reactions are a common side effect of EGRIFTA WR but may sometimes be serious. Change (rotate) your injection site to help lower your risk for injection site reactions. Call your healthcare provider for medical advice if you have any of the following symptoms around the area of the injection site:
  - redness
  - itching
  - pain
  - irritation
  - bruising or bleeding
  - rash
  - swelling
- **increased risk of death in people who have critical illnesses because of heart or stomach surgery, trauma or serious breathing (respiratory) problems** has happened when taking certain amounts of growth hormone.

The most common side effects of EGRIFTA WR include:

- pain in legs and arms
- muscle pain

These are not all the possible side effects of EGRIFTA WR. 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 1-833-23THERA (1-833-238-4372).

How should I store EGRIFTA WR 11.6 mg vials, Bacteriostatic Water for Injection, syringes, needles and alcohol swabs?

- You will be given two boxes (Medication Box and Injection Box) from the pharmacy when you get your prescription of EGRIFTA WR:
  - Store the 11.6 mg EGRIFTA WR vials in the Medication Box they come in, at room temperature between 68°F to 77°F (20°C to 25°C).
  - Store the Bacteriostatic Water for Injection, syringes, needles and alcohol swabs that come in the Injection Box at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep EGRIFTA WR vials out of the light. Do not freeze.
- After mixing and injecting on the first day, keep the EGRIFTA WR vial in your Medication Box, at room temperature at 20°C to 25°C (68°F to 77°F).
  - Throw away (discard) any unused EGRIFTA WR vial **7 days after mixing**.
  - Throw away (discard) any Bacteriostatic Water for Injection left in the bottle **28 days after first use**.
- **Do not use** EGRIFTA WR after the expiration date (EXP) printed on the carton and vial labels.

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

General information about the safe and effective use of EGRIFTA WR.

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

You can ask your healthcare provider or pharmacist for information about EGRIFTA WR that is written for health professionals.

What are the ingredients in EGRIFTA WR?

Active ingredient: tesamorelin (as an acetate salt)

Inactive ingredients: hydrochloric acid, hydroxypropyl betadex, mannitol, sodium hydroxide

EGRIFTA WR does not contain any preservative. Bacteriostatic Water for Injection contains benzyl alcohol as preservative.

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For more information about EGRIFTA WR, go to www.EGRIFTASV.com or call toll-free at 1-833-23THERA (1-833-238-4372).

This Patient Information has been approved by the U.S. Food and Drug Administration Revised: 03/2025