

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  **EGRIFTA ASSIST®** toll-free at 1-844-EGRIFTA (1-844-347-4382).

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 or contact

 **EGRIFTA ASSIST[®]** toll-free at 1-844-EGRIFTA (1-844-347-4382).

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.

Manufactured by: Jubilant HollisterStier General Partnership, 16751 Trans-Canada Highway, Montreal, Québec, Canada H9H 4J4

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Instructions for Use

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

Be sure that you read, understand, and follow this “Instructions for Use” before using EGRIFTA[®]. Your healthcare provider should show you how to mix and inject EGRIFTA[®] before you inject it for the first time. Ask your healthcare provider if you have any questions.

Keep this leaflet in case you need to look at it again later.

Important information for use of EGRIFTA[®]

- After mixing EGRIFTA[®] with Sterile Water for Injection, it should look clear and colorless, with no particles in it. Do not use EGRIFTA[®] if it looks cloudy, discolored, or if you see particles in it. Talk to your healthcare provider if you have any questions.
- Do not use EGRIFTA[®] after the date on the Medication Box and EGRIFTA[®] vial.
- Do not use a syringe or needle more than 1 time.
- **Do not share your EGRIFTA[®] needles with another person. You may give an infection to them or get an infection from them.**
- Sharing of needles can result in the transmission of infectious diseases, such as HIV. Do not share your EGRIFTA[®] syringe with another person, even if the needle is changed.
- If you are missing any supplies from your Medication Box or Injection Box, or if anything looks damaged call your pharmacist or contact  **EGRIFTA ASSIST**[®] toll-free 1-844-EGRIFTA (1-844-347-4382) right away.

Preparing for your EGRIFTA[®] injection

Step 1: Find a well-lit, clean, and flat surface, such as a table.

Step 2: Gather your supplies:

- Medication Box that contains 60 EGRIFTA[®] powder vials
- Injection Box that contains the following:
 - a) 30 10-mL bottles of Sterile Water for Injection, used for mixing
 - b) 30 sterile 3-mL syringes with sterile needle already attached
 - c) 30 individual 1½" 18-gauge sterile needles, used for mixing
 - d) 30 individual ½" 27-gauge injection needles

- Other Supplies Needed
 - Alcohol pads
 - Sterile gauze
 - A “sharps container” or a puncture resistant container for throwing away used needles and syringes after you are done with them.

Material included in Injection Box (a, b, c, d) and Medication Box (e):

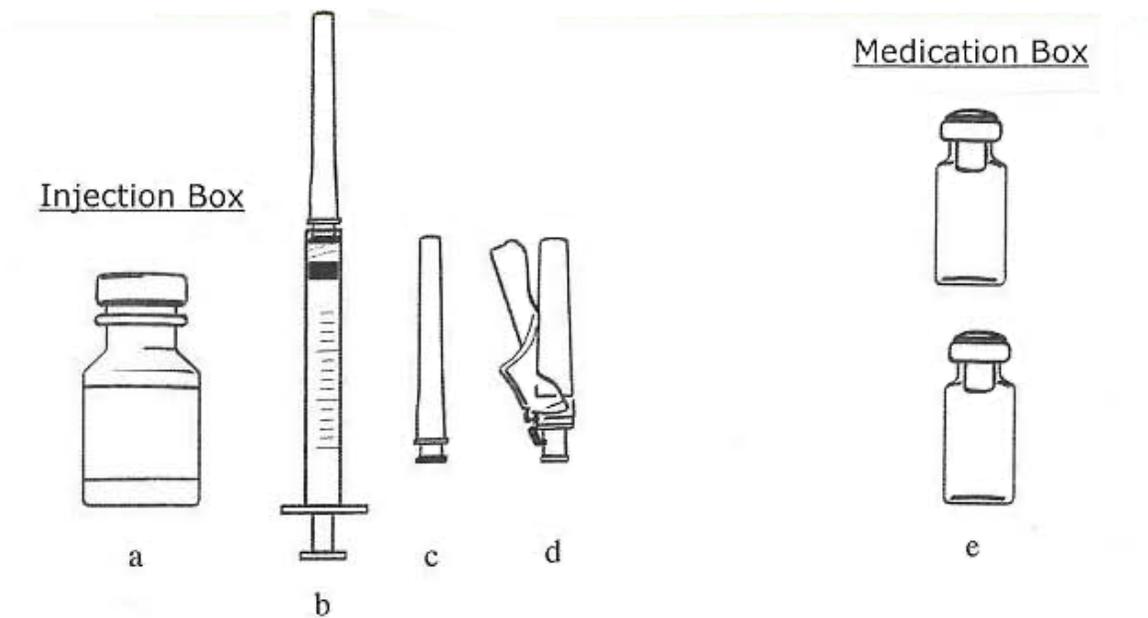


Figure A

Step 3: Take out the following from your Injection Box:

- A Sterile Water for Injection bottle (Figure A, a)
- A syringe with needle already attached (Figure A, b)
- A 1½" 18-gauge needle (Figure A, c)
- A ½" 27-gauge injection needle (Figure A, d)

Step 4: Take 2 EGRIFTA® vials (Figure A, e) from the Medication Box. Put the box with the remaining vials back in the refrigerator right away.

Step 5: Prepare to use your supplies:

- Wash your hands with soap and water. Dry your hands with a clean towel.

- Take off the plastic caps from the vials of EGRIFTA[®] and Sterile Water bottle.
- Clean the rubber stoppers on top of the 2 vials of EGRIFTA[®] and Sterile Water bottle with an alcohol swab.

How to mix EGRIFTA[®]

Step 1: Pick up the syringe with needle attached (Figure A, b), remove the protective cap and insert the needle through the rubber stopper of the bottle of Sterile Water (Figure A, a; see Figure B for illustration). Turn both upside down, and pull back the plunger until the liquid reaches the 2.2 mL mark on the syringe. (See Figure C)

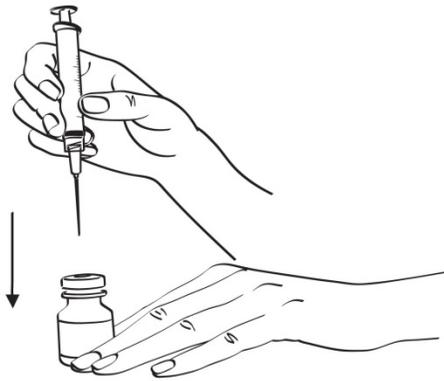


Figure B

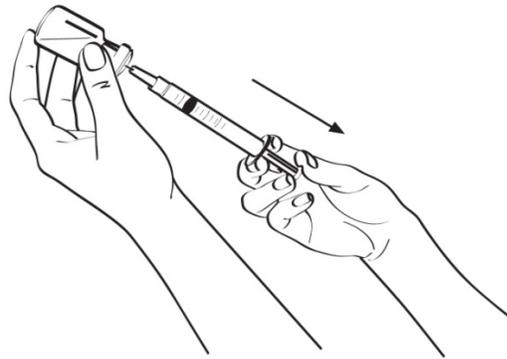


Figure C

Step 2: Take the syringe with needle attached out of the Sterile Water bottle and insert the needle into one of the EGRIFTA[®] vials. Push the plunger in slowly on a slight angle so water goes down the inside wall of the EGRIFTA[®] vial instead of directly onto the powder to avoid foaming. (See Figure D)



Figure D

Step 3: While keeping the syringe with needle attached in the vial and the vial upright, roll the vial gently in your hands for 30 seconds, until the Sterile Water and EGRIFTA[®] powder are mixed well. Do **not** shake the vial. (See Figure E)

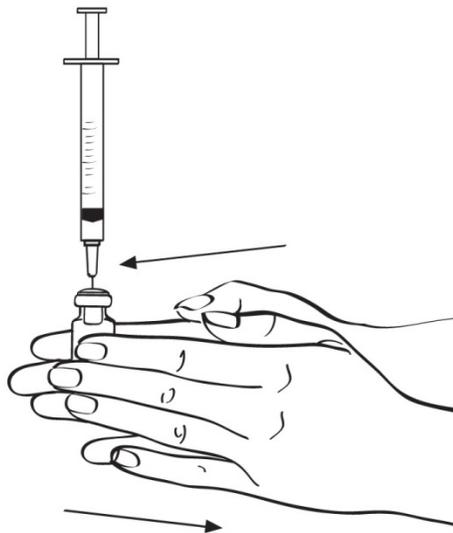


Figure E

Step 4: Still keeping the syringe with needle attached in the vial, turn both until the syringe is straight up. Pull down on the syringe until you see just the tip of the needle going through the rubber stopper, then pull back on the

plunger until all the liquid inside the vial goes into the syringe. The level of medicine in the syringe should be around the 2.2 mL syringe mark. (See Figure F)



Figure F

Step 5: Take the needle out of the vial. (See Figure G)

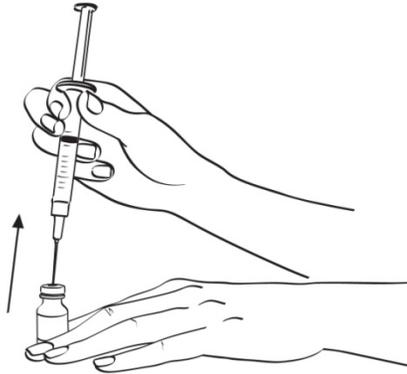


Figure G

Step 6: Place the needle cap on its side against a clean flat surface. Without touching the needle, hold the syringe and slide the needle carefully into the protective cap (See Figure H). Push the cap all the way or until it snaps shut (See Figure I). Do not touch the cap until it covers the needle completely.

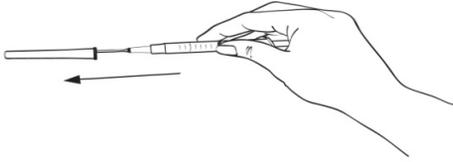


Figure H

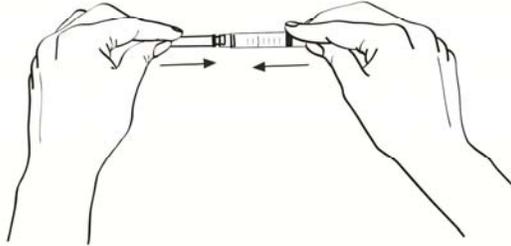


Figure I

Step 7: With the cap on the needle, remove the needle by holding the syringe firmly and twisting the cap counterclockwise (to the left). (See Figure J)

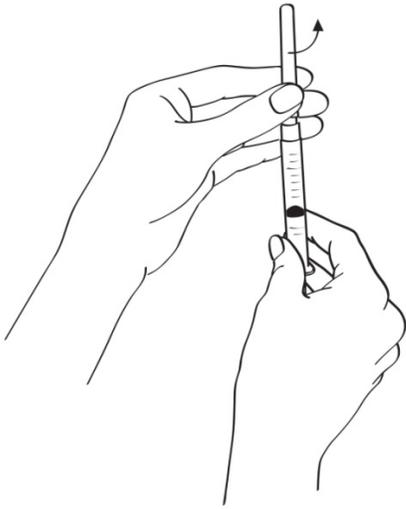


Figure J

Step 8: Place the 1½" 18-gauge mixing needle (Figure A, c), with its protective cap in place, onto the syringe. Twist the cap clockwise (to the right) until it is tight. (See Figure K)

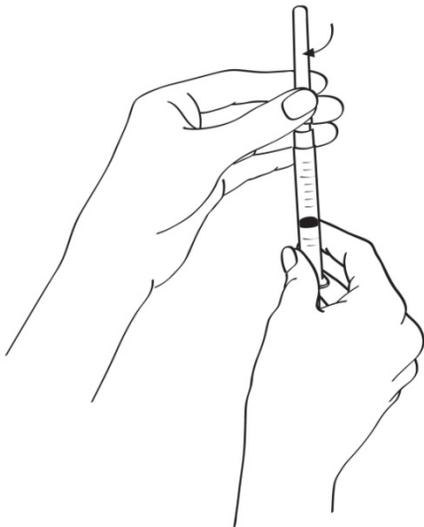


Figure K

Step 9: Remove the protective cap and insert the needle into the second *EGRIFTA*[®] vial (Figure A, e). Push the plunger in slowly on a slight angle so

that the mixture goes down the inside wall of the EGRIFTA[®] vial instead of directly into the powder to avoid foaming (see Figure L).



Figure L

Step 10: Keeping the syringe in the vial and the vial upright, roll the vial gently in your hands for 30 seconds, until the water and powder are mixed well. (Do **not** shake the vial.) The solution should look clear and colorless, with no particles in it. (See Figure M)

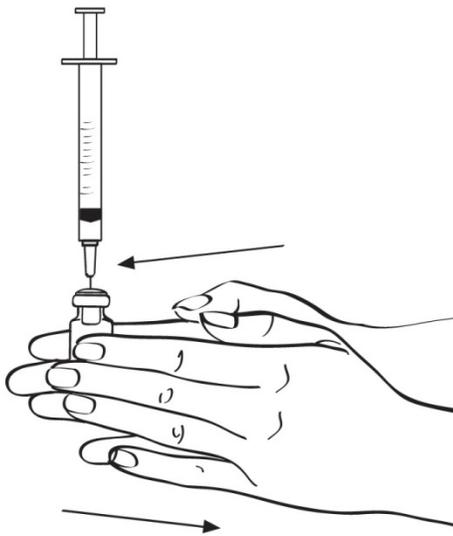


Figure M

Step 11: Still keeping the syringe in the vial, turn both until the syringe is straight up. Pull down on the syringe until you see just the tip of the needle going through the rubber stopper, then pull back on the plunger until all the

liquid inside the vial goes into the syringe. The level of medicine in the syringe should be around the 2.2 mL syringe mark. (See Figure N)

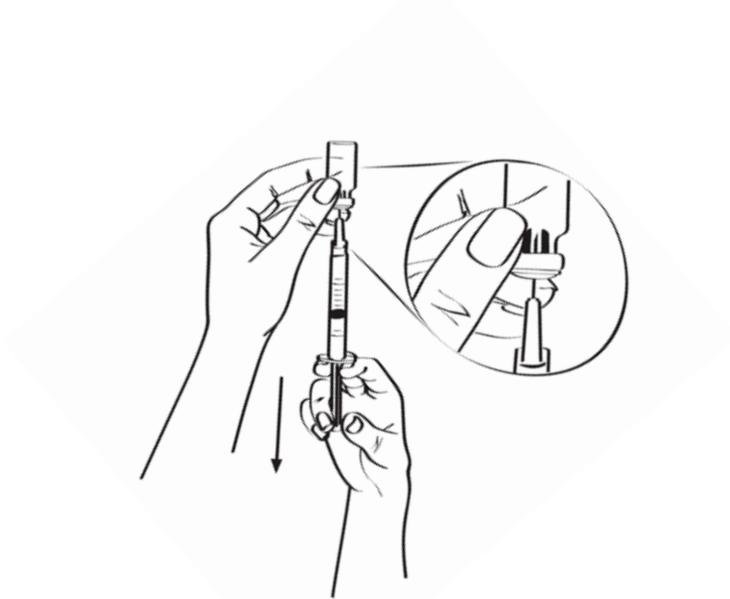


Figure N

Step 12: Take the needle out of the vial. (See Figure O)

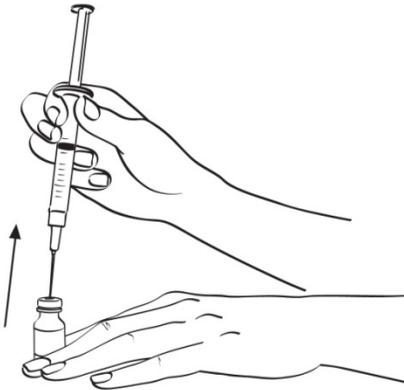


Figure O

Step 13: Place the needle cap on its side against a clean flat surface. Without touching the needle, hold the syringe and slide the needle carefully into the protective cap (See Figure P). Push the cap all the way until it snaps shut (See Figure Q). Do not touch the cap until it covers the needle completely.

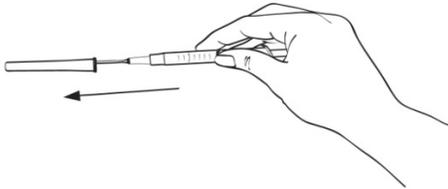


Figure P

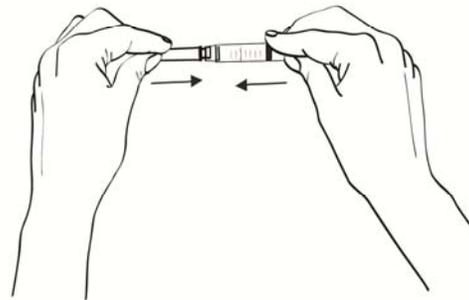


Figure Q

Step 14: With the needle cap on the needle, remove the mixing needle by holding the syringe firmly and twisting the cap counterclockwise (to the left). (See Figure R)

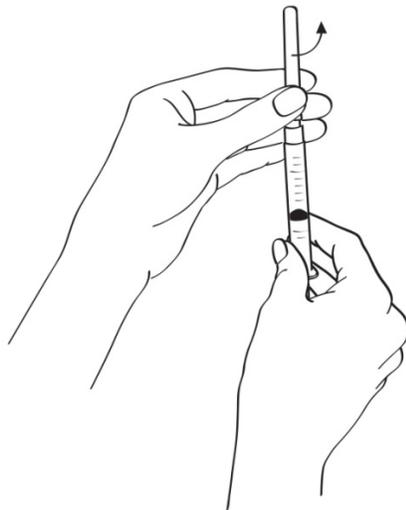


Figure R

Step 15: Place the injection needle (Figure A, d), with its white protective cap in place, onto the syringe. Hold the syringe firmly and twist the cap clockwise (to the right) until it closes securely. (See Figure S)

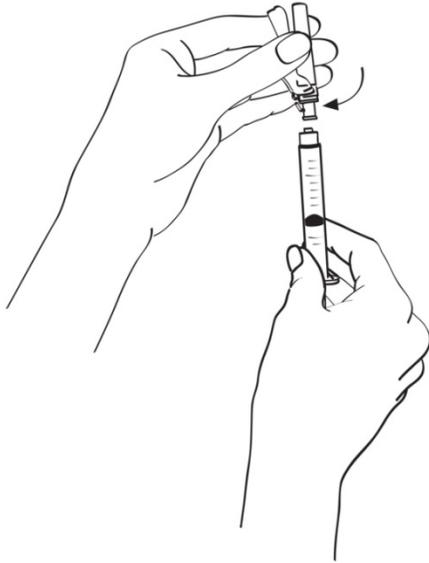


Figure S

Where do I inject EGRIFTA®?

You should inject EGRIFTA® into the skin on your stomach (abdomen). (See Figure T)

- Pick an injection site that is around your belly button to the left or right.
- Stay away from any area with scar tissue, bruises, reddening, infection, or irritation.
- Avoid areas with any hard bumps from previous injections.
- Change your injection site from one day to the next. This may help prevent bruising or irritation. You may want to keep a note of the date and location of each daily injection to help you remember.



Figure T

How to inject EGRIFTA®

- Pick up the syringe and pull the cap straight off the injection needle. Do **not** twist it. (See Figure U)



Figure U

- Tap the syringe gently with your finger to force any air bubbles to rise to the top. Press the plunger to push bubbles out. (See Figure V)



Figure V

- Clean the injection site you have selected with an alcohol swab and let it dry. Hold the syringe in one hand. Use your other hand to hold a cleaned fold of skin for your injection. Hold the skin between your thumb and fingers. (See Figure W)



Figure W

- Hold the syringe at a right angle to the skin, like a dart. Push the injection needle into the skin with a quick motion. Most of the needle should go beneath the skin surface. (See Figure X)

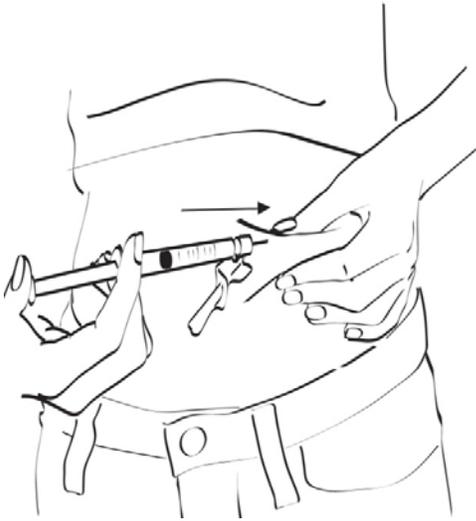


Figure X

- Remove your hand from the pinched area of skin after the needle goes in. Make sure the needle stays in the skin. (See Figure Y)



Figure Y

- Slowly push the plunger all the way down until all of the medicine in the syringe has been injected under the skin.
- Pull the injection needle out of your skin when the syringe is empty:
 - Be careful to pull it out at the same angle you put it in
 - Flip back the pink needle shield until it snaps, covering the injection needle completely. Keep pressing until you hear a click, that means the injection needle is protected. (See Figure Z)

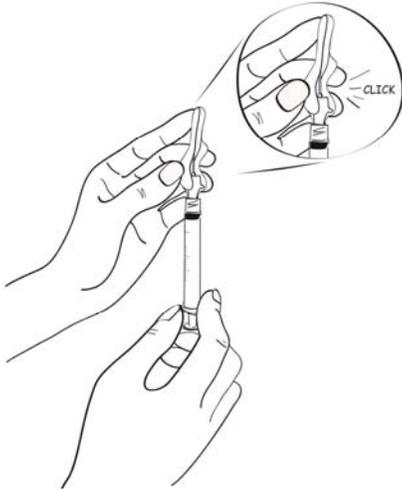


Figure Z

- Use a piece of sterile gauze to rub the injection site clean. If there is bleeding, apply pressure to the injection site with gauze for 30 seconds. If bleeding continues, apply a bandage to the site.

How should I dispose of the used syringes, needles, bottles and vials?

- **Do not** recap the needle or remove the needle from the syringe after you inject EGRIFTA[®].
- Put your used EGRIFTA[®] needles and syringes in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and syringes in your household trash.**
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, and
 - properly labeled to warn of hazardous waste inside the container.

- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and pens. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.
- **Do not** dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. **Do not** recycle your used sharps disposal container.
- If you accidentally prick another person with a used needle, that person should be informed to contact a healthcare provider right away about the accident.
- Keep the sharps container away from children and pets.

If you have any questions, call your healthcare provider. You can call

 **EGRIFTA ASSIST**® toll-free 1-844-EGRIFTA (1-844-347-4382) or visit the EGRIFTA® Web site at: www.EGRIFTA.com for more information.

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 Injection 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 away from light.
- Do not freeze.
- 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.
- Do not use EGRIFTA® after the expiration date printed on the Medication Box and vial labels.

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

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

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured by: Jubilant HollisterStier General Partnership, 16751 Trans-Canada Highway, Montreal, Québec, Canada H9H 4J4



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