Patient Instructions for Use

EGRIFTA™ (eh-GRIF-tuh)
(tesamorelin for injection)

Be sure that you read, understand, and follow these Patient 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. 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 AXIS Center toll-free at 1-877-714-2947 right away.

Preparing for your EGRIFTA™ injection

- Find a well-lit, clean, and flat surface, such as a table.
- 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 (BD 3 mL Syringe)
    c) 30 individual 1½" 18-gauge sterile needles, used for mixing (BD Blunt Fill Needle)
    d) 30 individual ½" 27-gauge injection needles (BD Eclipse™ Injection Needle)
  - Alcohol pads
  - Sterile gauze
  - A “sharps container” or a puncture resistant container for throwing away needles after you are done with them. The container should be made from hard plastic or metal. Make sure it has a lid. You can also put used syringes or empty vials of medicine in the container.
Material Included in Injection Box and Medication Box:

- **Injection Box**
  - a) Sterile Water for Injection bottle
  - b) Syringe with needle already attached (BD 3 mL Syringe)
  - c) 1½" 18-gauge needle for mixing (BD Blunt Fill Needle)
  - d) ½" injection needle (BD Eclipse™ Injection Needle)
  - e) EGRIFTA™ powder medication vials (two)

- **Medication Box**

**Figure A**

You should have the materials as illustrated and lettered in the figure A above:

- a) Sterile Water for Injection bottle
- b) Syringe with needle already attached (BD 3 mL Syringe)
- c) 1½" 18-gauge needle for mixing (BD Blunt Fill Needle)
- d) ½" injection needle (BD Eclipse™ Injection Needle)
- e) EGRIFTA™ powder medication vials (two)

- Take out the following from your Injection Box:
  - o A Sterile Water for Injection bottle (Figure A, a)
  - o A syringe with needle already attached (Figure A, b)
  - o A 1½" 18-gauge needle (Figure A, c)
  - o A ½" 27-gauge injection needle (Figure A, d)

- Take two EGRIFTA™ vials (Figure A, e) from the Medication Box. Put the box with the remaining vials back in the refrigerator right away.

- Prepare to use your supplies:
  - o Wash your hands with soap and water. Dry your hands with a clean towel.
  - o Take off the plastic caps from the vials of EGRIFTA™ and Sterile Water.
  - o Clean the rubber stopper on top of the vial(s) 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](image1)

![Figure C](image2)

Step 2: Take the syringe with needle attached out of the Sterile Water bottle and insert the needle into the EGRIFTA™ vial. 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](image3)

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 F

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)
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
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)

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)
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 water goes down the inside wall of the EGRIFTA vial instead of directly into the powder to avoid foaming (see 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 facing upright. Carefully 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: Carefully take the needle out of the vial. (See 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.)

With the needle cap on the needle, remove the mixing needle by holding the syringe firmly and twisting the cap counterclockwise. (See Figure R)
**Step 14:** Place the safety injection needle (Figure A, d), with its 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 below 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](image)

**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](image)

- 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)
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)
- 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)

- 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 needle shield until it snaps, covering the injection needle completely. Keep pressing until you hear a click, that means the injection needle is protected (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?

• 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.

• Never reuse or recycle needles or syringes.

• Never throw used needles, syringes, or the sharps container into the trash.

• Throw away used syringes, needles, EGRIFTA™ vials and Sterile Water for Injection bottle in a puncture-proof container, sharps container, or a hard container like a coffee can.

• Speak to your pharmacist or other healthcare provider about the proper disposal of the sharps container and all other used materials. There may be local or state laws about how to throw away used needles and syringes.

• Keep the sharps container away from children and pets.

If you have any questions, call your healthcare provider. You can call AXIS Center toll free at 1-877-714-2947 or visit the EGRIFTA™ Web site at www.EGRIFTA.com for more information.

How do I store EGRIFTA™?

• EGRIFTA™ has two boxes:
  • Store the Medication Box of EGRIFTA™ vials in the refrigerator between 2°C and 8°C (36°F and 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.

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

EGRIFTA™ is a trademark of Theratechnologies Inc.

Distributed by: EMD Serono, Inc., Rockland, MA 02370, USA
Date: 2010-09-27