

PATIENT INFORMATION
EGRIFTA SV® (eh-GRIF-tuh ESS-vee)
(tesamorelin) for injection
for subcutaneous use
2 mg vial

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

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

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

EGRIFTA SV is not for weight loss management.

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

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

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

Who should not use EGRIFTA SV?

Do not use EGRIFTA SV 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 SV.
- are allergic to tesamorelin or any of the ingredients in EGRIFTA SV. See the end of this leaflet for a complete list of ingredients in EGRIFTA SV.
- are pregnant or plan to become pregnant. EGRIFTA SV can harm your unborn baby. If you become pregnant, stop using EGRIFTA SV and talk with your healthcare provider.

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

Before using EGRIFTA SV, 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 SV 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 SV 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 SV.

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 SV?

- Read the detailed "Instructions for Use" that comes with EGRIFTA SV before you start using it. Your healthcare provider will show you how to inject EGRIFTA SV.
- Use EGRIFTA SV exactly as your healthcare provider tells you to use it.
- Inject EGRIFTA SV 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 SV into scar tissue, bruises or your belly button.
- **Do not share your EGRIFTA SV 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 SV?

EGRIFTA SV may cause serious side effects, including:

- **increase risk of new cancer in HIV positive patients or your cancer coming back (reactivation).** Stop using EGRIFTA SV 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 SV.
- **swelling (fluid retention).** EGRIFTA SV 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 SV, 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 SV and during your treatment with EGRIFTA SV.
- **serious allergic reaction.** Some people using EGRIFTA SV may have an allergic reaction. **Stop using EGRIFTA SV and get emergency medical help right away if you have any of the following symptoms:**

- a rash over your body
- shortness of breath or trouble breathing
- hives
- fast heartbeat
- itching
- swelling of your face or throat
- feeling of faintness or fainting
- reddening or flushing of the skin

• **injection site reactions.** Injection site reactions are a common side effect of EGRIFTA SV 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
- irritation
- swelling
- itching
- bruising or bleeding
- pain
- rash

• **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 SV include:

- pain in legs and arms
- muscle pain

These are not all the possible side effects of EGRIFTA SV. 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 SV 2 mg vials, Sterile Water for Injection, syringes and needles?

- You will be given two boxes from the pharmacy when you get your prescription of EGRIFTA SV:
 - Store the 2 mg EGRIFTA SV vials in the Medication Box they come in, at room temperature at 20°C to 25°C (68°F to 77°F).
 - Store the Sterile Water for Injection, syringes and needles that come in the Injection Box at room temperature at 20°C to 25°C (68°F to 77°F).
- Keep EGRIFTA SV vials out of the light.
- After mixing, use EGRIFTA SV **right away**. Throw away any unused EGRIFTA SV after mixing.
- **Do not** store, freeze or refrigerate EGRIFTA SV after it has been mixed with the Sterile Water.
- Throw away any Sterile Water for Injection left in the bottle after use.
- Do not use EGRIFTA SV after the expiration date (EXP) printed on the carton and vial labels.

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

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

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use EGRIFTA SV for a condition for which it was not prescribed. Do not give EGRIFTA SV 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 SV that is written for health professionals.

What are the ingredients in EGRIFTA SV?

Active ingredient: tesamorelin (as an acetate salt)

Inactive ingredients: histidine, hydrochloric acid, mannitol, polysorbate 20, sucrose

EGRIFTA SV does not contain any preservative.

Manufactured by Theratechnologies Inc., 2015 Peel Street, Suite 1100, Montréal, Québec, Canada H3A 1T8 US License No. 2091 for Theratechnologies Inc.

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

Instructions for Use


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

This Instructions for Use contains step-by-step information on how to use the **2 mg vial** of EGRIFTA SV. **Each 2 mg vial of EGRIFTA SV must be mixed with 0.5 mL of the Sterile Water for Injection** provided in the Injection Box given to you by the pharmacy. **Use only one EGRIFTA SV 2 mg vial from the Medication Box** to prepare your dose. The recommended **dose of EGRIFTA SV is 1.4 mg (0.35 mL)**.

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

Keep this Instructions for Use in case you need to look at it again later.

Important information for use of EGRIFTA SV

- **Do not** use a syringe or needle more than 1 time.
- **Do not share your 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.**
- If you are missing any supplies from the boxes given to you by the pharmacy or if any of the supplies look damaged, call your pharmacist or contact  **· THERA patient support[®]** toll-free at 1-833-23THERA (1-833-238-4372) right away.

Preparing for your EGRIFTA SV injection

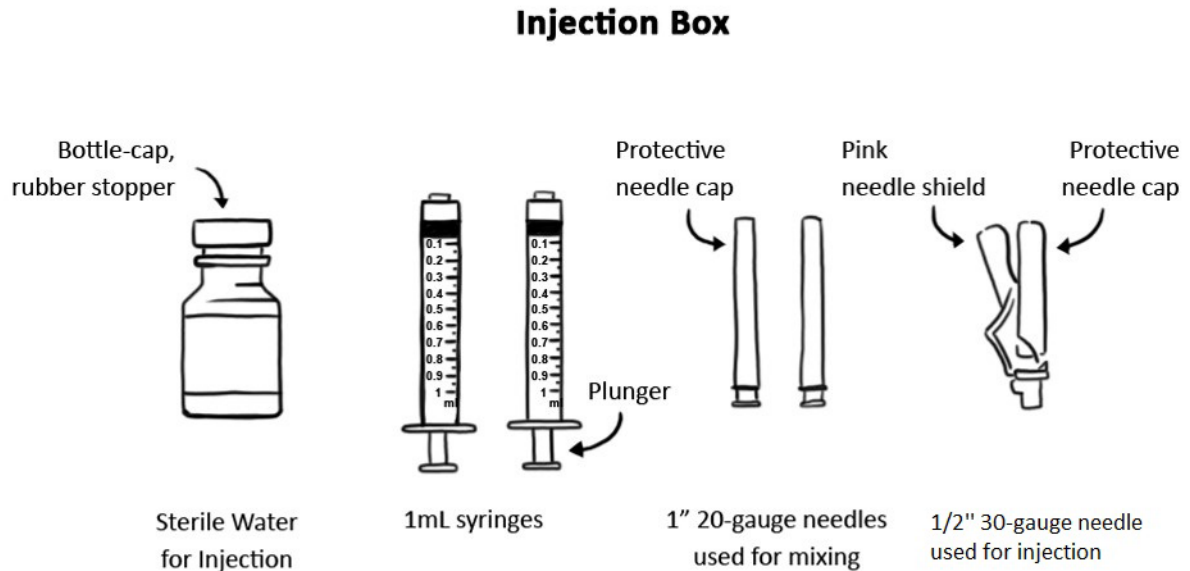
Step 1: Find a well-lit, clean, and flat surface, such as a table.

Step 2: Gather your supplies:

- Medication Box that contains 30 EGRIFTA SV 2 mg single-dose vials
- Injection Box that contains the following:
 - 30 single-dose 10 mL bottles of Sterile Water for Injection, used for mixing
 - 60 sterile 1 mL syringes
 - 60 sterile 1" 20-gauge needles, used for mixing
 - 30 sterile ½" 30-gauge needles, used for injection
- Other Supplies Needed
 - Two alcohol pads
 - One sterile gauze
 - One adhesive bandage

- Sharps disposal container or a puncture resistant container for throwing away used needles and syringes after you are done with them. (See “**How should I dispose of the used syringes, needles, bottles and vials?**”)

For each injection using EGRIFTA SV 2 mg vial you will need: (See Figure A)



Medication Box

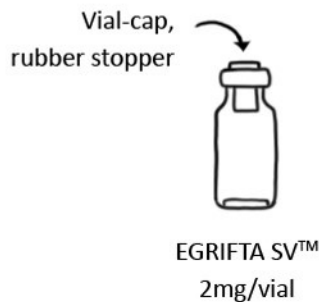


Figure A

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

- One Sterile Water for Injection bottle
- Two 1 mL syringes
- Two 1" 20-gauge needles used for mixing
- One 1/2" 30-gauge needle used for injection

Step 4: Take **1 vial** of EGRIFTA SV 2 mg from the Medication Box.

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 EGRIFTA SV 2 mg vial and the Sterile Water for Injection bottle.
- Clean the rubber stoppers on the top of the EGRIFTA SV 2 mg vial and Sterile Water for Injection bottle with an alcohol pad.

How to mix EGRIFTA SV 2 mg vial

Step 1: Place a 1" 20-gauge needle used for mixing, with its protective needle cap in place, onto a 1 mL syringe. Hold the syringe firmly and twist the needle cap clockwise (to the right) until it closes securely. (See Figure B)

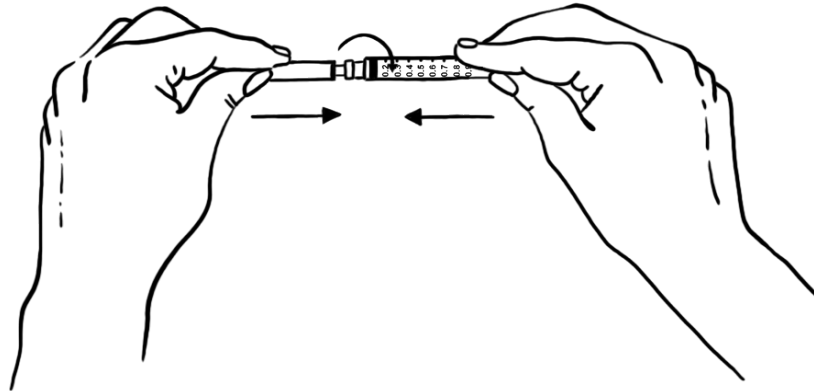


Figure B

Step 2: Carefully remove the protective needle cap by pulling it straight off. **Do not** twist the needle cap.

Insert the needle through the rubber stopper of the Sterile Water for Injection bottle. (See Figure C)

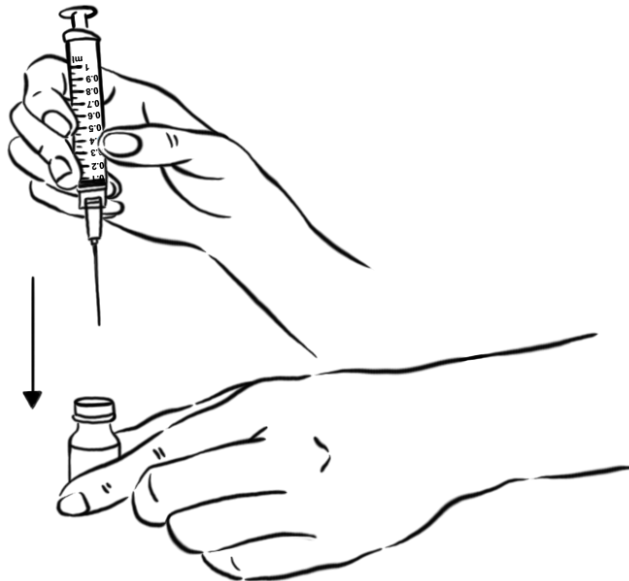


Figure C

Step 3: With the needle still in the Sterile Water for Injection bottle, turn the bottle and syringe upside down. Pull back the plunger until the Sterile Water reaches the 0.5 mL mark on the syringe. (See Figure D)

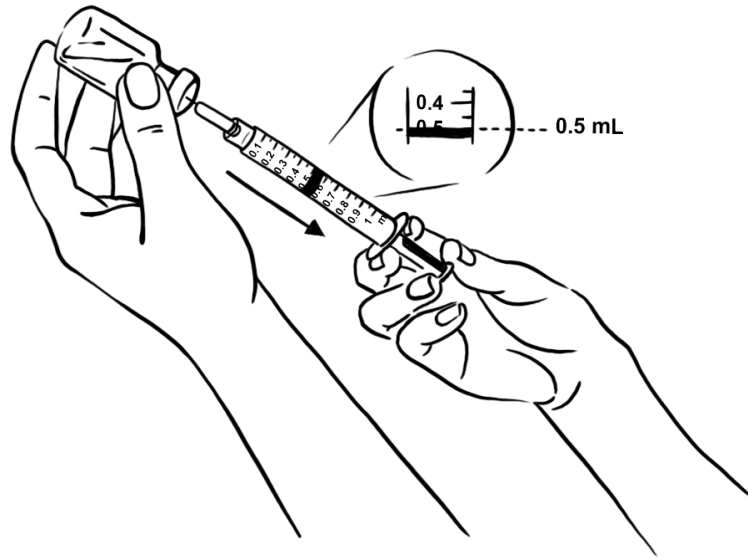


Figure D

Step 4: Remove the syringe with needle attached from the Sterile Water bottle. Throw away the bottle containing the unused Sterile Water for Injection. (See “**How should I dispose of the used syringes, needles, bottles and vials?**”)

Insert the needle into the rubber stopper of the EGRIFTA SV 2 mg vial. With the needle at a slight angle, slowly push the plunger of the syringe all the way down so that the Sterile Water goes down the inside wall of the EGRIFTA SV 2 mg vial instead of directly onto the powder to avoid foaming. (See Figure E)

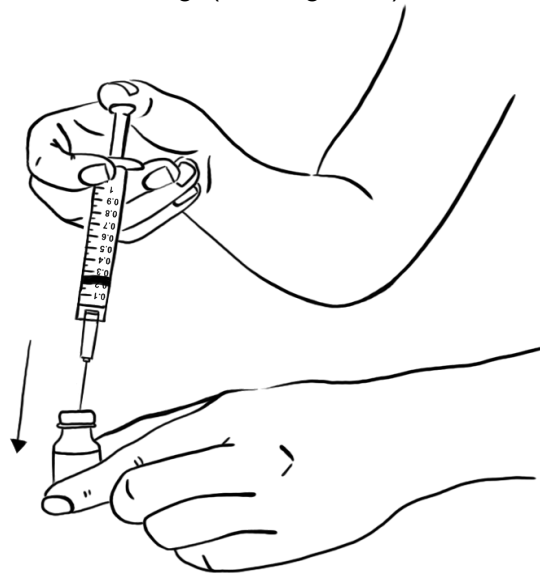


Figure E

Step 5: Remove the needle from the EGRIFTA SV 2 mg vial (see Figure F) and throw away the syringe and needle. (See “**How should I dispose of the used syringes, needles, bottles and vials?**”)



Figure F

Step 6: Roll the EGRIFTA SV 2 mg vial gently in your hands for 30 seconds, until the Sterile Water and EGRIFTA SV powder are mixed well. **Do not** shake the vial. (See Figure G)

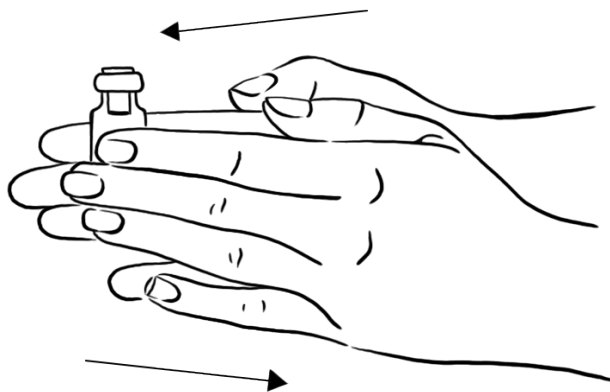



Figure G

Note:

- After mixing, the solution should look clear and colorless, with no particles in it.
- Do not use EGRIFTA SV if it looks cloudy, discolored, or if you see particles in it.
- Call your healthcare provider, pharmacist, or contact  **THERA patient support** toll-free at 1-833-23THERA (1-833-238-4372) right away if the solution is cloudy, discolored, or contains particles.

Step 7: Place a new unused 1" 20-gauge needle used for mixing, with its protective needle cap in place, onto a new unused 1 mL syringe. Hold the syringe firmly and twist the needle cap clockwise (to the right) until it closes securely. (See Figure H)

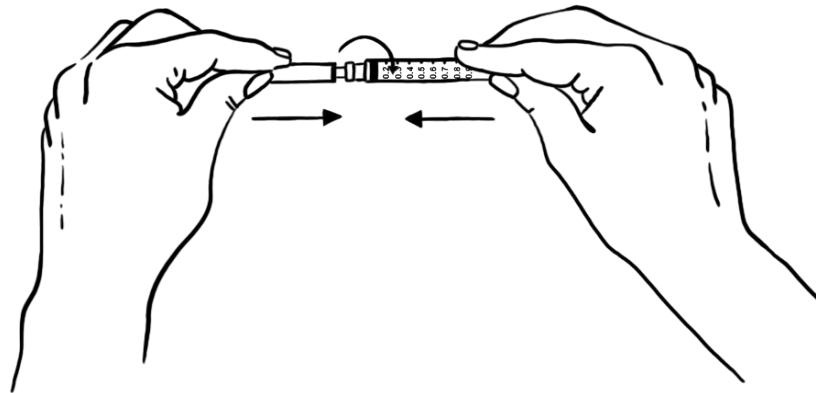


Figure H

Step 8: Carefully remove the protective needle cap by pulling it straight off. **Do not** twist the needle cap.

Do not throw away the needle cap.

Insert the needle through the rubber stopper of the EGRIFTA SV 2 mg vial. (See Figure I)

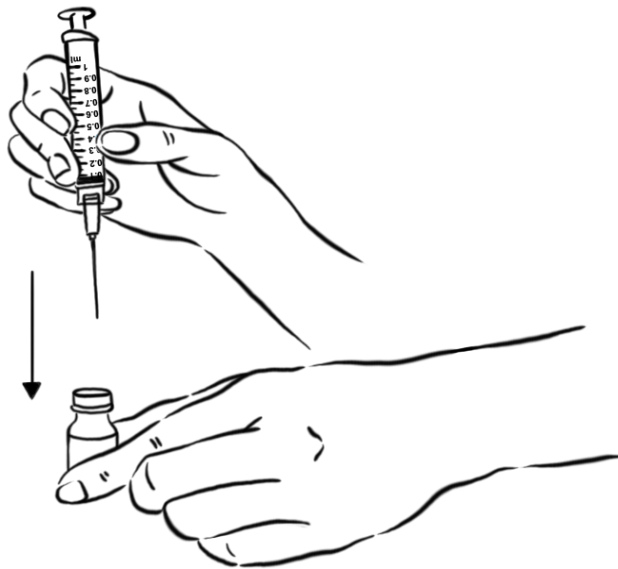


Figure I

Step 9: With the needle still in the EGRIFTA SV 2 mg vial, turn the vial and syringe upside down.

Pull the syringe back until you see just the tip of the needle going through the rubber stopper. Pull back on the plunger of the syringe until **all** of the liquid inside the vial is in the syringe. The medicine should be at around the 0.4 mL mark on the syringe. (See Figure J)

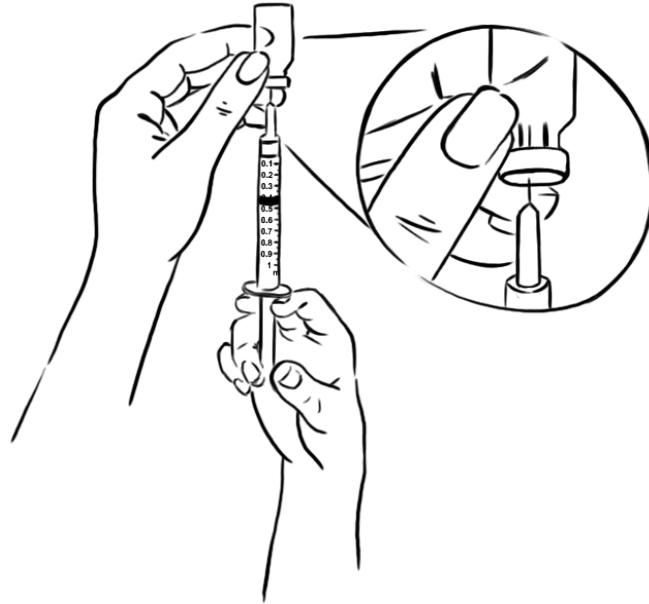


Figure J

Step 10: Remove the needle from the vial. (See Figure K)

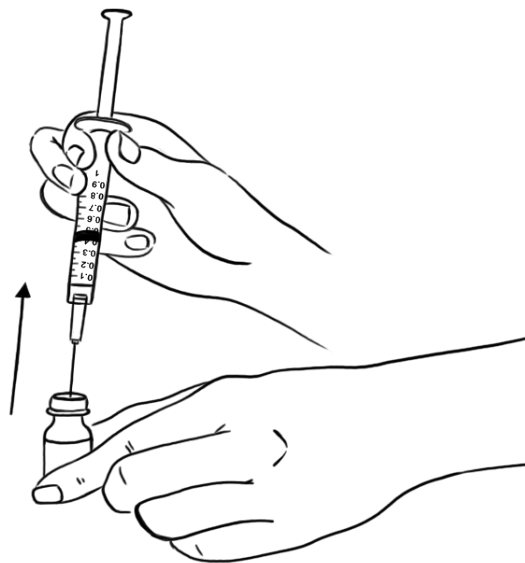


Figure K

Step 11: Place the protective needle cap on its side on a clean flat surface. Without touching the needle, hold the syringe and slide the needle carefully into the needle cap. (See Figure L)

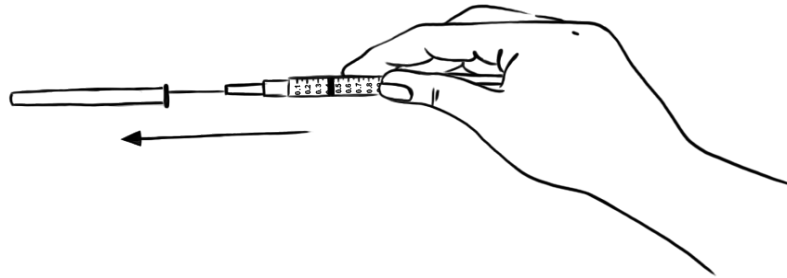


Figure L

Step 12: Push the protective needle cap all the way in or until it snaps shut (See Figure M). **Do not** touch the needle cap until it covers the needle completely.

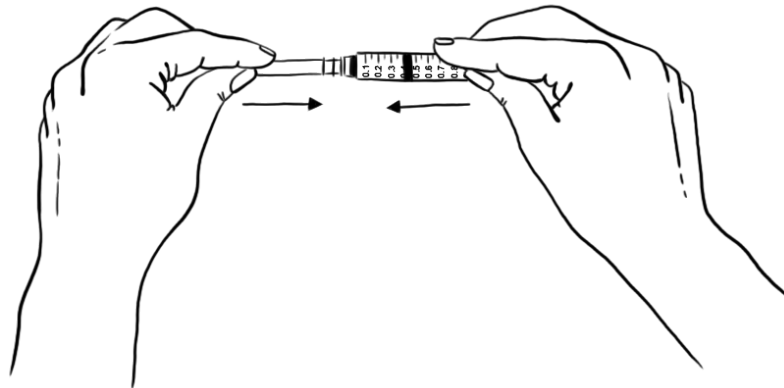


Figure M

Step 13: With the protective needle cap securely on the needle, remove the needle by holding the syringe firmly and twisting the needle cap counterclockwise (to the left). (See Figure N) Throw away the needle. (See “**How should I dispose of the used syringes, needles, bottles and vials?**”)

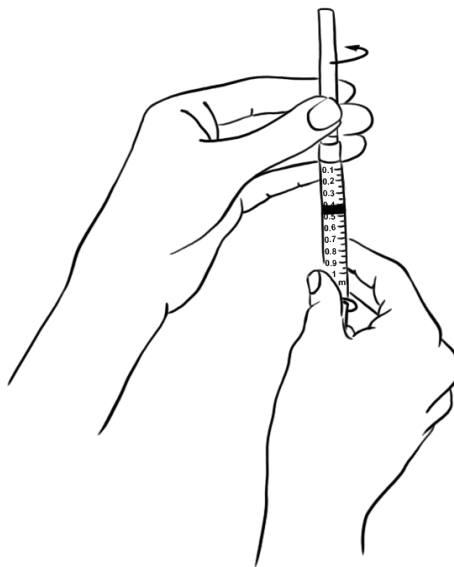


Figure N

Step 14: Place a ½" 30-gauge needle to be used for your injection, with its protective needle cap and pink needle shield in place, onto the syringe. Hold the syringe firmly and twist the needle cap and pink needle shield clockwise (to the right) until it closes securely. (See Figure O)

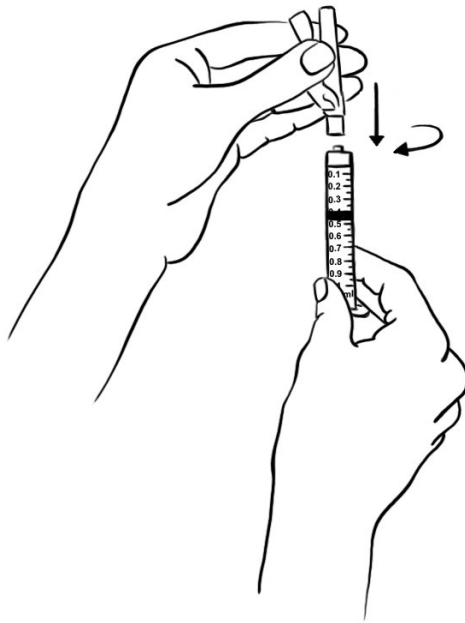


Figure O

Where do I inject EGRIFTA SV 2 mg vial?

Inject EGRIFTA SV into the stomach-area (abdomen). (See Figure P)

- Choose an injection site that is at least 2 inches (5 cm) away from your belly button. (See the shaded area in Figure P)
- **Do not** inject into areas with scar tissue or bruises.
- **Do not** inject into your belly button.
- Avoid areas with any hard bumps from previous injections.
- Rotate the site for each injection. This may help prevent bruising or irritation. You may want to write down the date and location of each daily injection to help you remember.

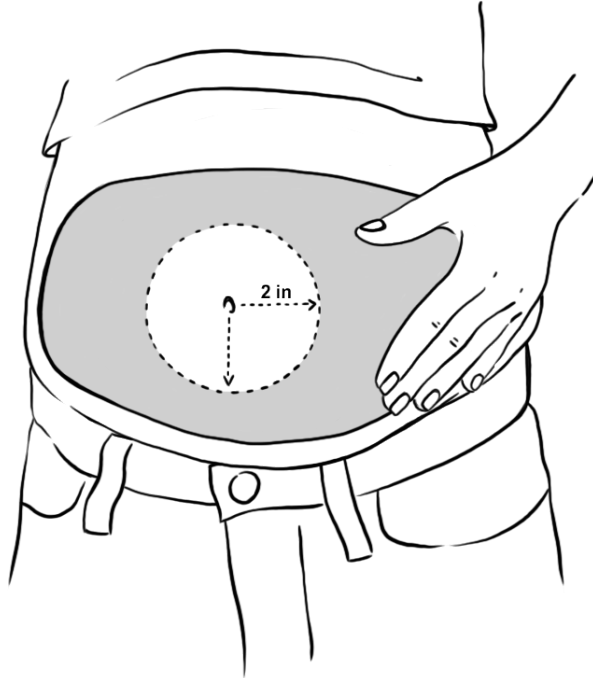


Figure P

How to inject your 1.4 mg dose of EGRIFTA SV

Do not remove the needle cap until you are ready to inject.

Step 1: Hold the syringe with the needle facing up. Pull the pink needle shield down away from the white protective needle cap.

Carefully remove the needle cap by pulling it straight off the needle. **Do not** twist the needle cap. (See Figure Q)

Do not touch the needle.

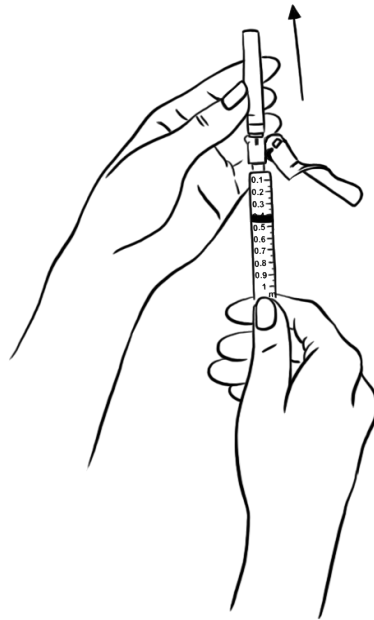


Figure Q

Step 2: Tap the syringe gently with your finger to force any air bubbles to rise to the top. Slowly push up on the plunger to remove any air and bubbles and until the medicine in the syringe is at the 0.35 mL mark of the syringe. (See Figure R)

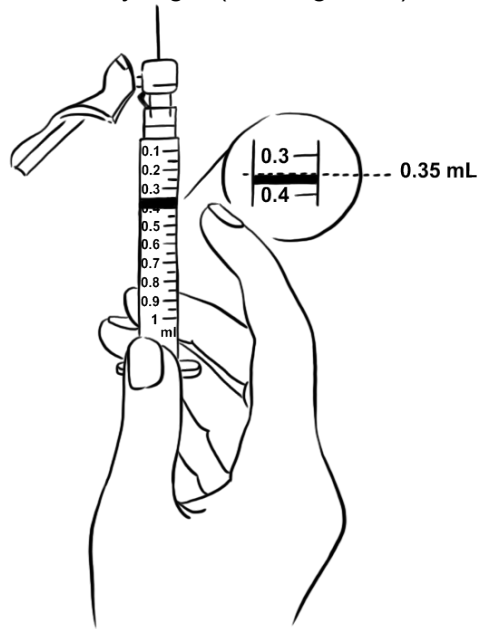


Figure R

Step 3: Clean the injection site you have selected with an alcohol pad and let it dry. Hold the syringe in one hand. With your other hand, gently pinch a fold of skin at your cleaned injection site. Hold the skin between your thumb and fingers. (See Figure S)

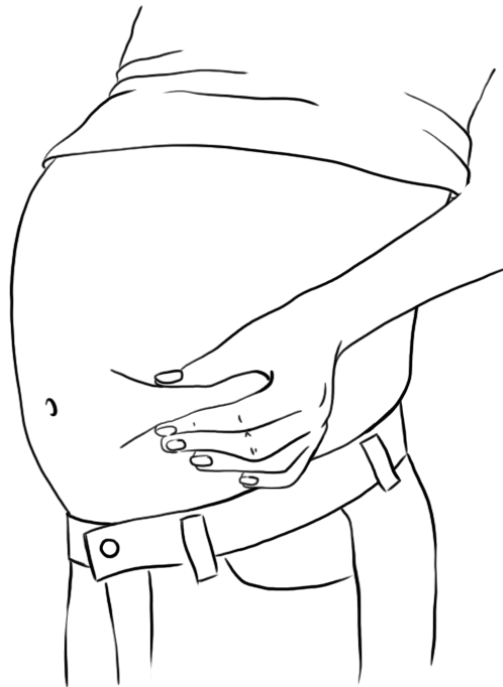


Figure S

Step 4: Hold the syringe at a 90 degree angle to the skin. With a quick, dart-like motion, insert the needle straight into the skin. Most of the needle should go beneath the skin. (See Figure T)

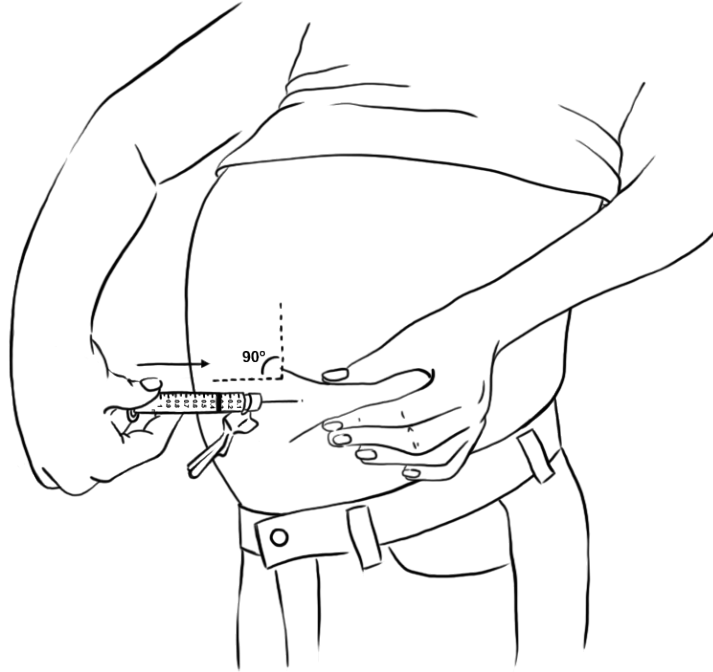


Figure T

Step 5: Remove your hand from the pinched area of skin after the needle is inserted. Be careful not to remove the needle from the skin.

Step 6: Slowly push the plunger of the syringe all the way down until all of the medicine in the syringe has been injected. (See Figure U)

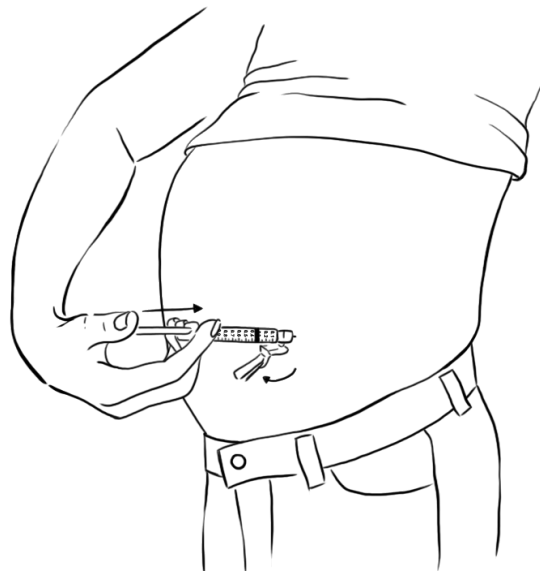


Figure U

Pull the needle out of your skin. Be careful to pull the needle out at the same angle as it was inserted.

Step 7: While holding the syringe in one hand, gently press the pink needle shield against a hard, flat surface until you hear a “click” and the injection needle is covered by the pink needle shield. (See Figure V)

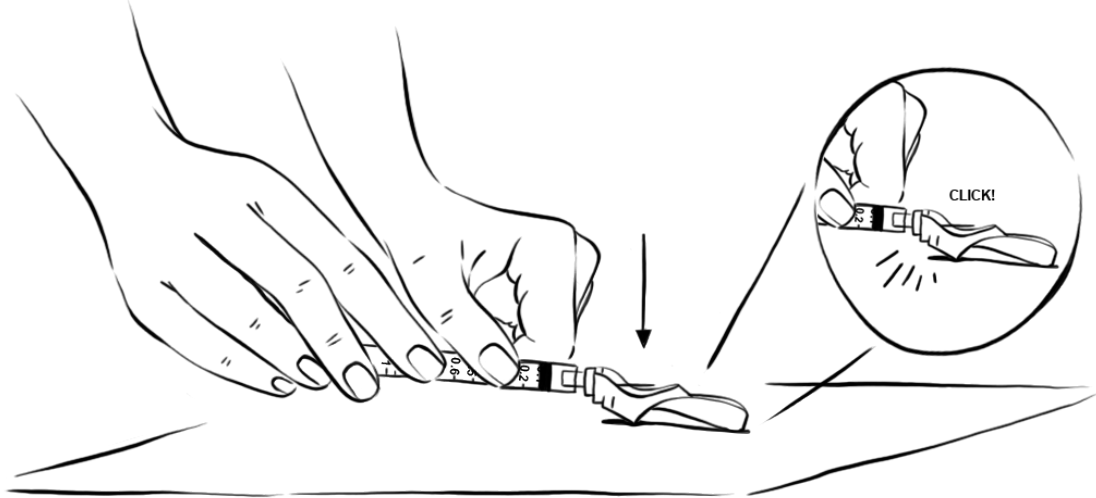


Figure V

- Apply pressure to the injection site with gauze for 30 seconds. If there is bleeding, apply an adhesive bandage to the site.
- Throw away the syringe. (See “**How should I dispose of the used syringes, needles, bottles and vials?**”)

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 SV.
- Put your used EGRIFTA SV 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 syringes. 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 another person receives a needle stick with a used needle, that person should be told to contact a healthcare provider right away.
- Keep the sharps container away from children and pets.

If you have any questions, call your healthcare provider.

You can call  **THERA patient support** toll-free at 1-833-23THERA (1-833-238-4372) or visit the EGRIFTA SV website at www.EGRIFTA.com for more information.

How should I store EGRIFTA SV 2 mg vials, Sterile Water for Injection, syringes and needles?

- You will be given 2 boxes from the pharmacy when you get your prescription of EGRIFTA SV:
 - Store the 2 mg EGRIFTA SV vials in the Medication Box they come in, at room temperature between 68°F to 77°F (20°C to 25°C).
 - Store the Sterile Water for Injection, syringes and needles that come in the Injection Box at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep EGRIFTA SV vials out of the light.
- After mixing, use EGRIFTA SV **right away**. Throw away any unused EGRIFTA SV after mixing.
- **Do not** store, freeze or refrigerate EGRIFTA SV after it has been mixed with the Sterile Water.
- Throw away any Sterile Water for Injection left in the bottle after use.
- Do not use EGRIFTA SV after the expiration date (EXP) printed on the carton and vial labels.

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

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



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Manufactured by: Theratechnologies Inc., 2015 Peel Street, Suite 1100, Montréal, Québec, Canada H3A 1T8 US Licence No. 2091 for Theratechnologies Inc.

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