

Instructions for Use


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

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)

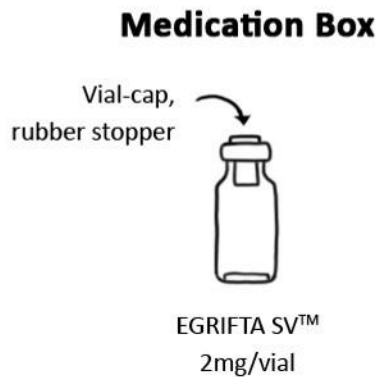
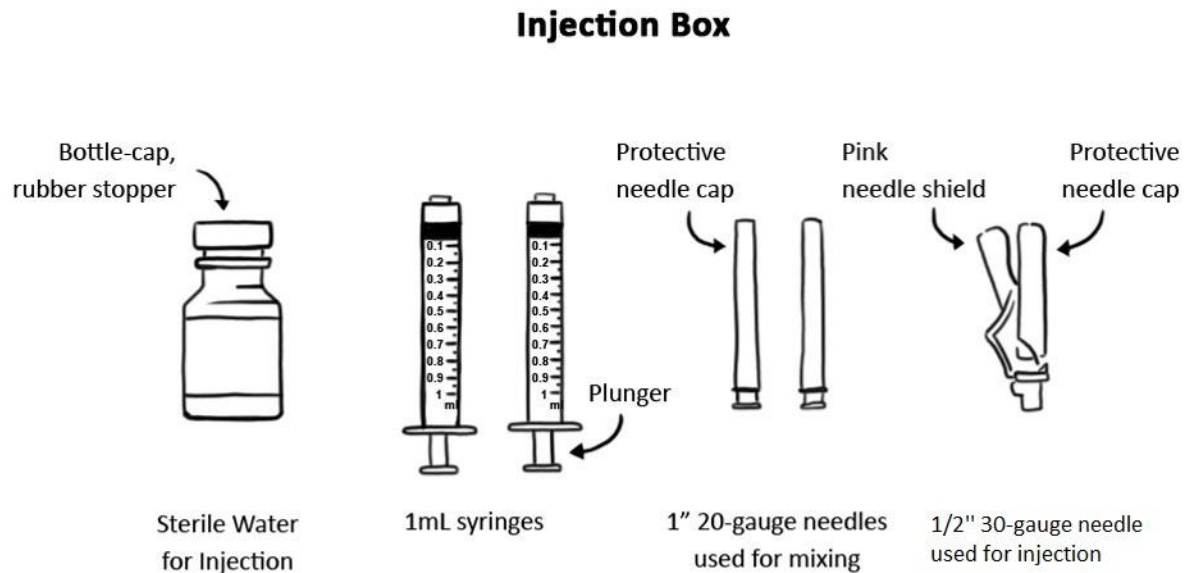


Figure A

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 ½" 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)

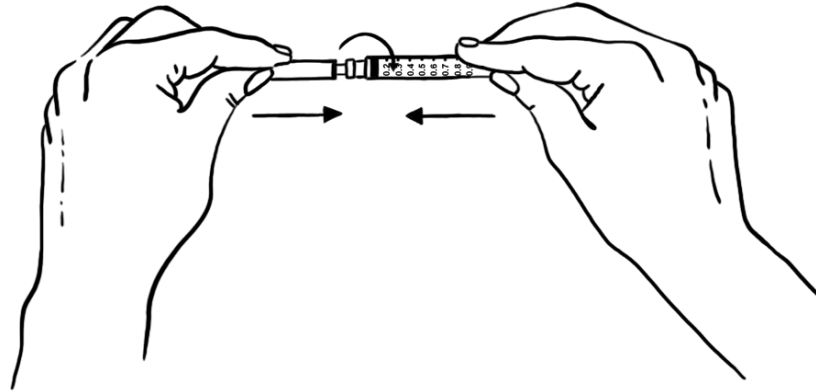


Figure B

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)

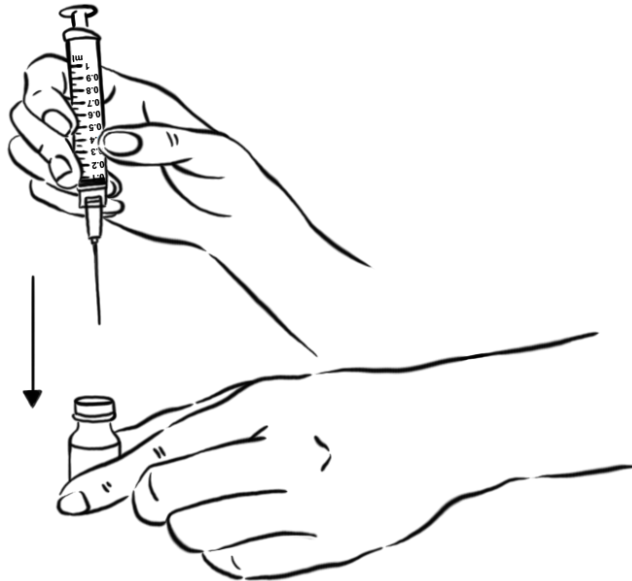


Figure C

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)

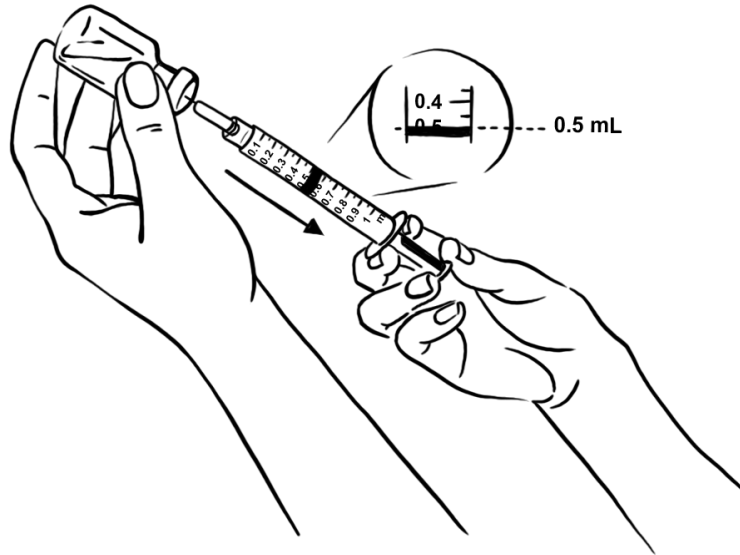


Figure D

- Throw away the bottle containing the unused Sterile Water for Injection. (See “**How should I dispose of the used syringes, needles, bottles and vials?**”)

Step 4: Remove the syringe with needle attached from the Sterile Water bottle. 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)

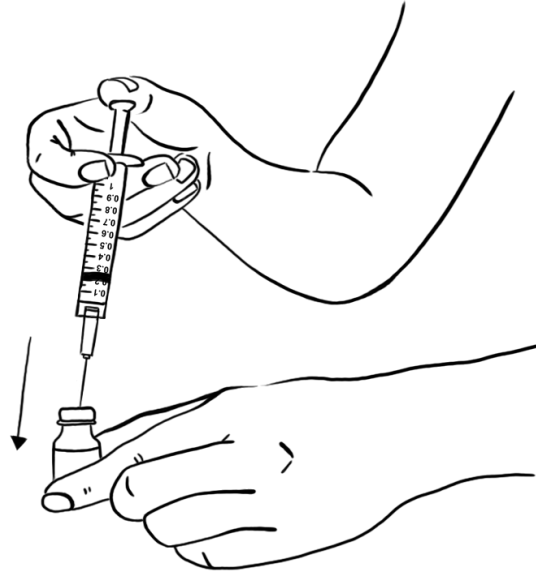


Figure E

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?**”)

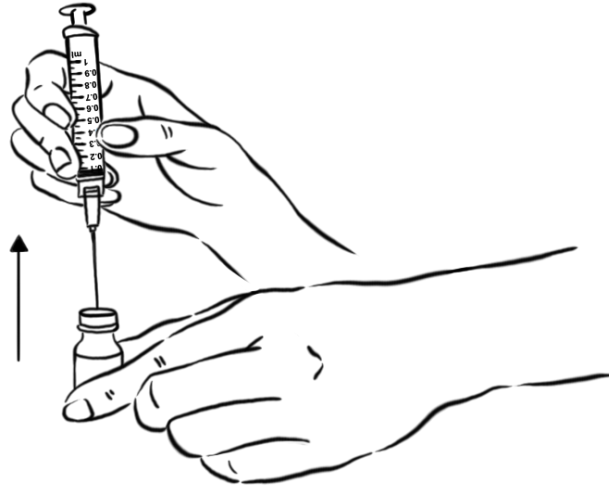


Figure F

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)

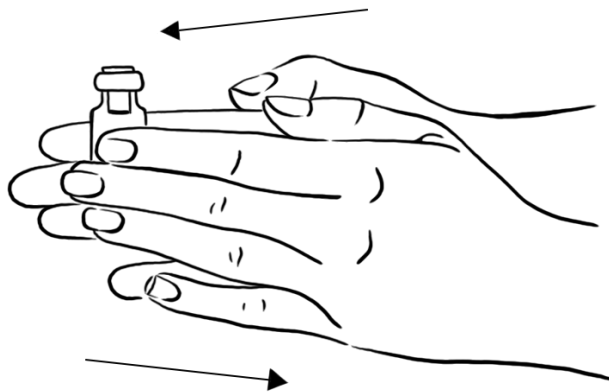



Figure G

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)

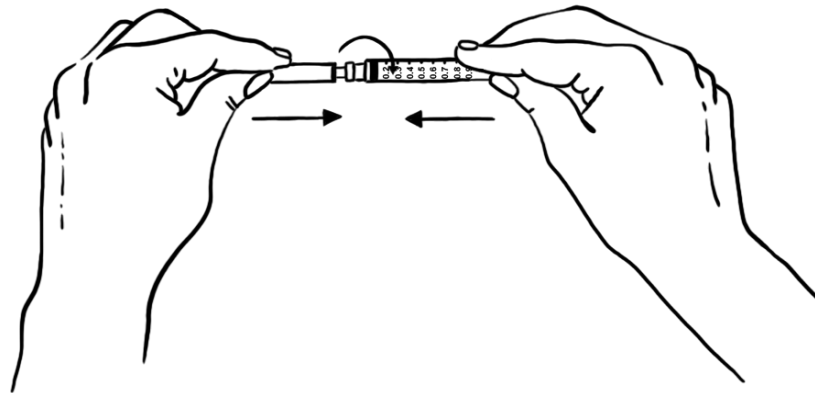


Figure H

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)

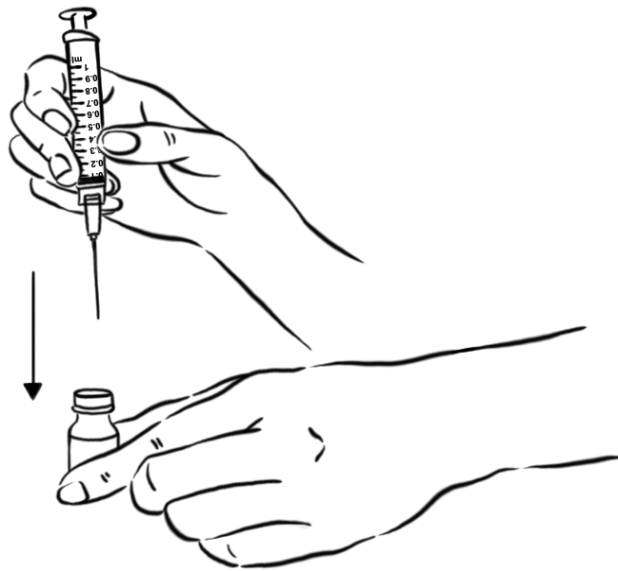


Figure I

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)

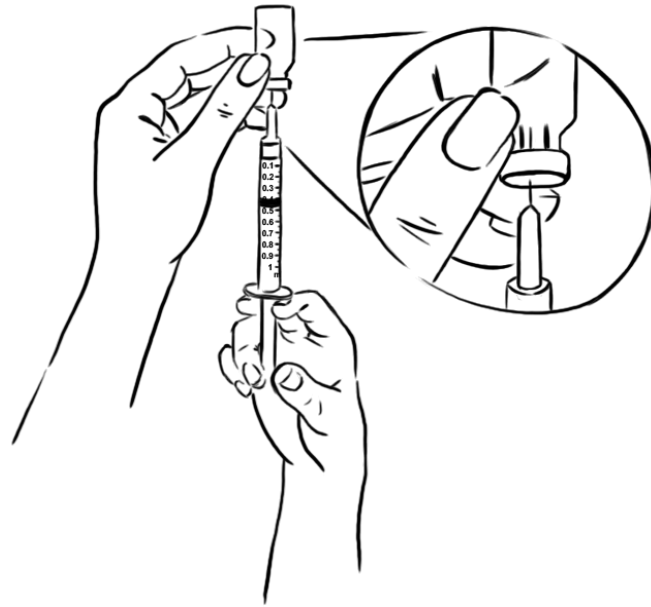


Figure J

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

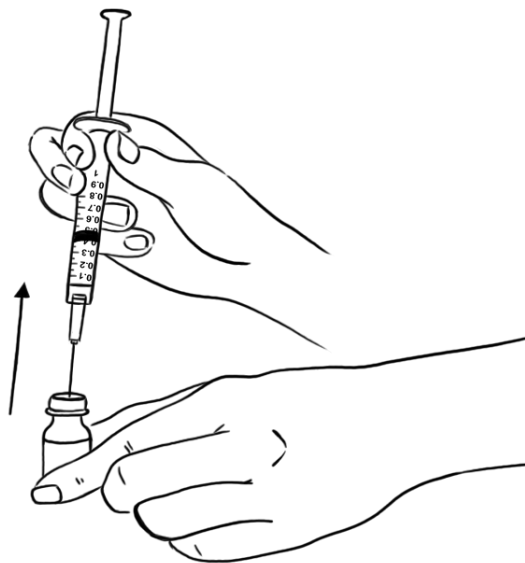


Figure K

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)

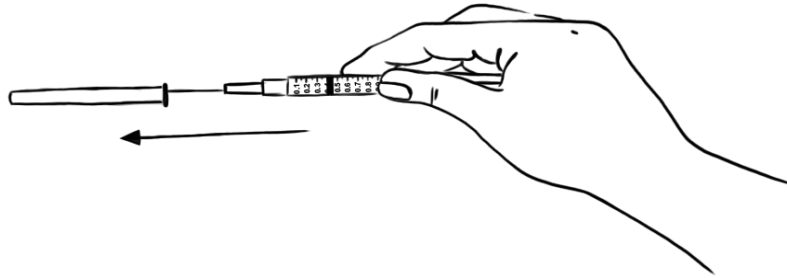


Figure L

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.

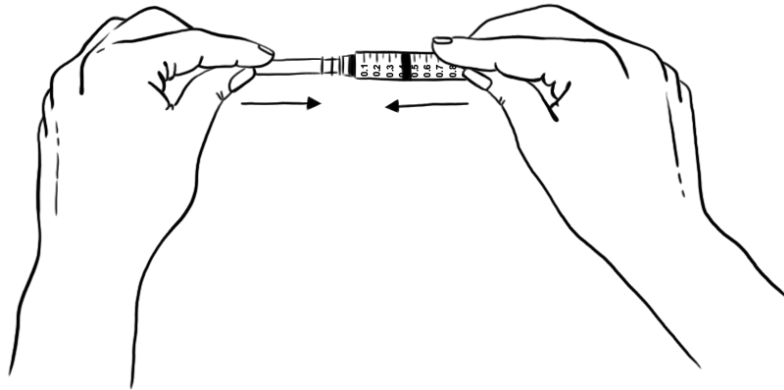


Figure M

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?**”)

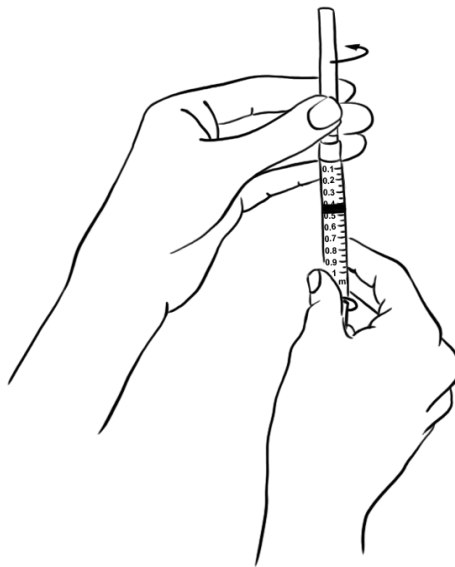


Figure N

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)

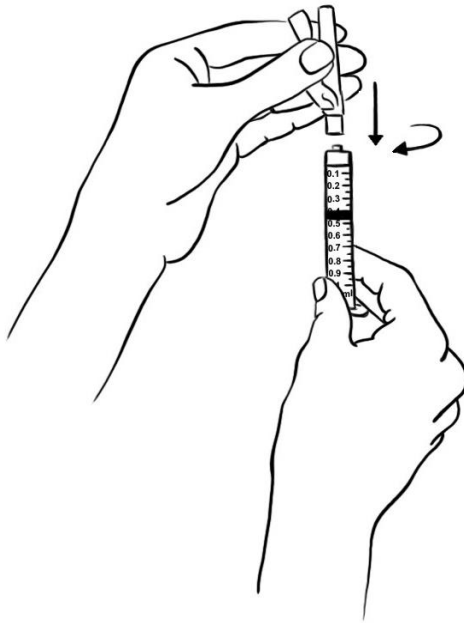


Figure O

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.

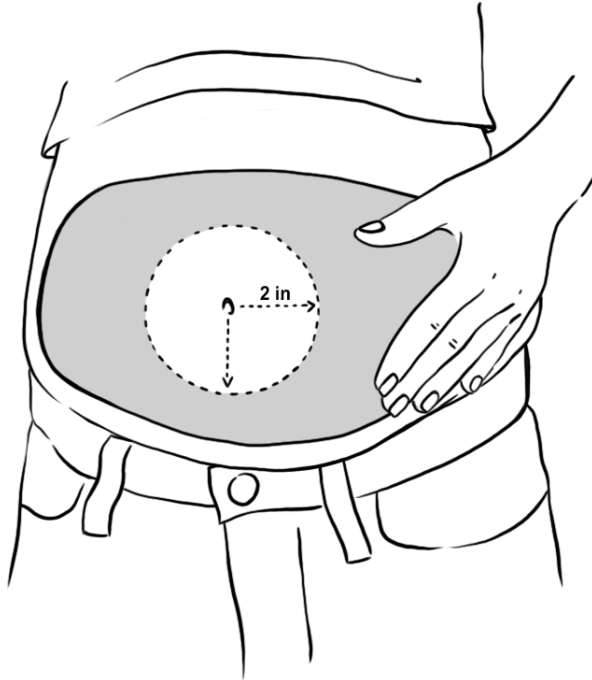


Figure P

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.

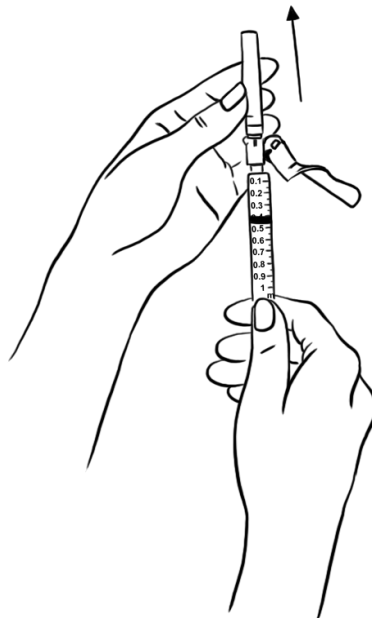


Figure Q

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)

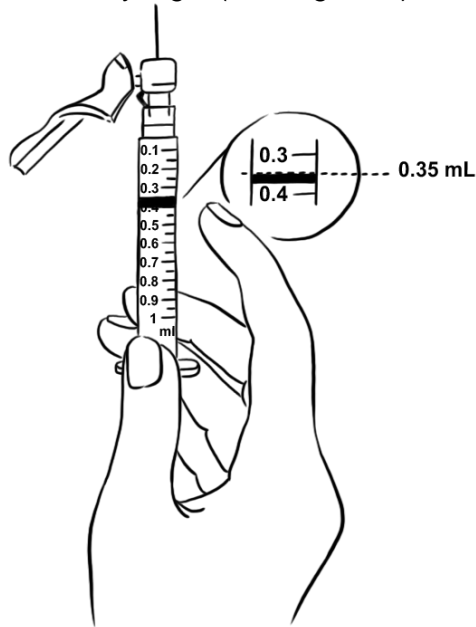


Figure R

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)

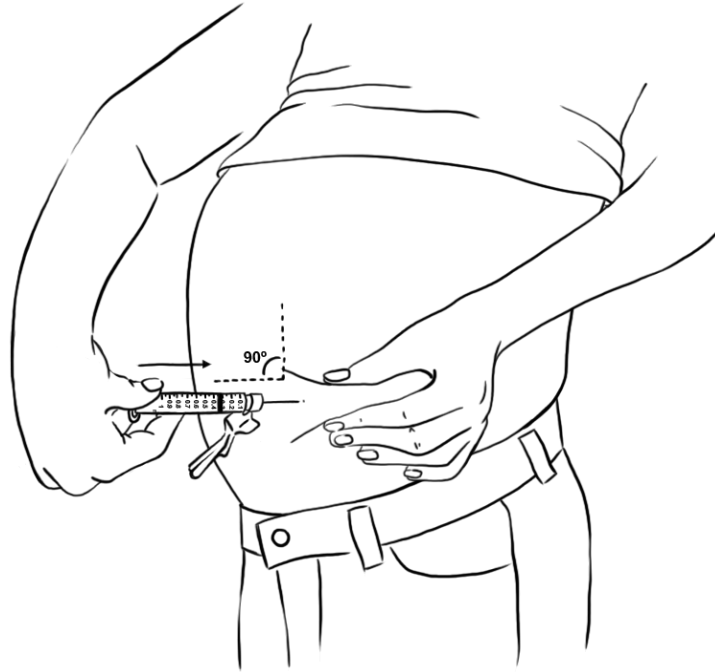


Figure T

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)

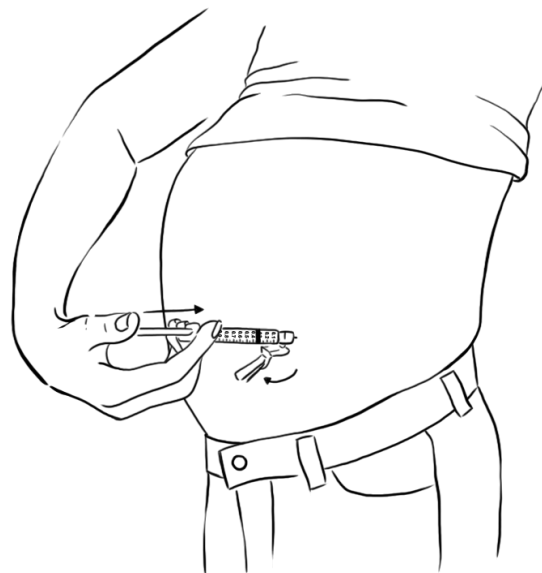


Figure U

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)

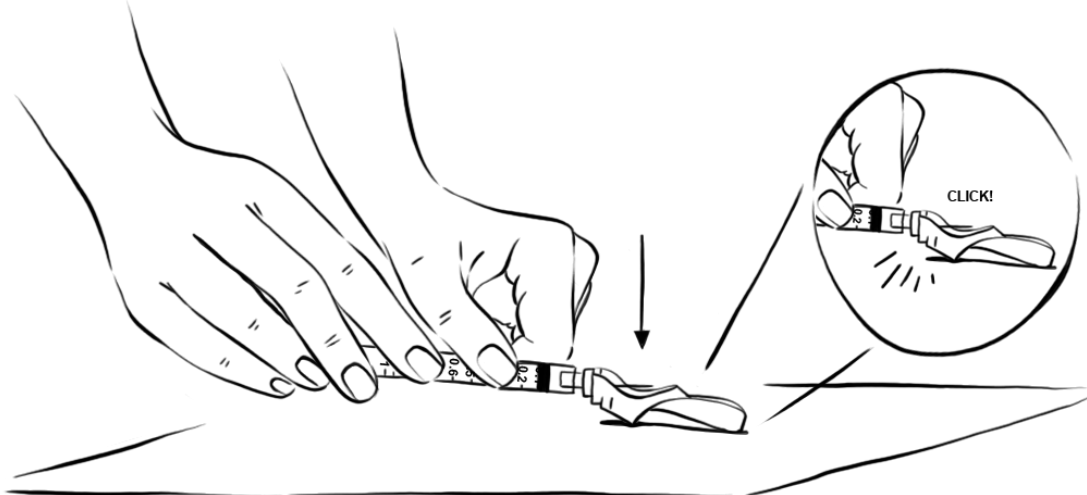


Figure V


- 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.EGRIFTASV.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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Distributed by: Theratechnologies Inc., Montréal, Québec, Canada H3A 1T8

Revised: 07/2019