



INSTRUCTIONS FOR USE

EGRIFTA WR™ [EH-GRIF-TUH DUB-UH-YOO-AHR]
(tesamorelin) for injection
for subcutaneous use

Note: This Instructions for Use contains information on how to mix and inject the **EGRIFTA WR 11.6 mg vial**.

Read and follow the steps for weekly mixing and daily injection of EGRIFTA WR 11.6 mg vial.

- Your healthcare provider should show you how to mix and inject EGRIFTA WR 11.6 mg vial before you inject it for the first time. Ask your healthcare provider if you have any questions.

Important Information You Need to Know Before Injecting EGRIFTA WR (11.6 mg) vial

- For **subcutaneous injection only** (inject directly under the skin).
- There are two EGRIFTA formulations (EGRIFTA WR and EGRIFTA SV) with different recommended dosages. **EGRIFTA WR and EGRIFTA SV are not substitutable.**
- The recommended **daily dose of EGRIFTA WR is 1.28 mg (0.16 mL).**
- One (1) EGRIFTA WR 11.6 mg vial must be mixed with 1.3 mL of the Bacteriostatic Water for Injection to prepare for 7 doses [for 7 consecutive daily injections (Day 1 to Day 7) of treatment].**
- Do not share your syringe or needles with other people. You may give other people a serious infection or get a serious infection from them.**
- Do not use a syringe or needle more than 1 time.**
- If supplies are missing, damaged or expired; or if you have any questions at any time during the mixing or the injection of EGRIFTA WR, call your pharmacist or **T: THERA patient support** toll-free at 1-833-23THERA (1-833-238-4372).

Storing of EGRIFTA WR

- Store the Medication Box at room temperature between 68°F to 77°F (20°C to 25°C) and keep the EGRIFTA WR vials out of the light.
- Store the Injection Box at room temperature at 68°F to 77°F (20°C to 25°C).
- Do not freeze or refrigerate EGRIFTA WR after it has been mixed with the Bacteriostatic Water for Injection.**
- Keep EGRIFTA WR and all medicines out of the reach of children.

Boxes Content

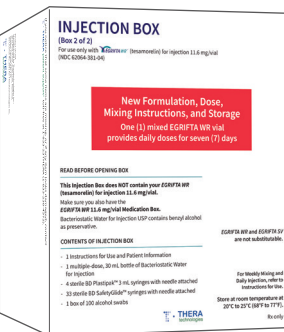
Medication Box



Supplies for 28 days:

- 4 single-patient use EGRIFTA WR 11.6 mg vials (**mix only 1 vial per week as per weekly mixing**)

Injection Box



Supplies for 28 days:

- 1 multiple-dose, 30 mL bottle of Bacteriostatic Water for Injection (**to be used for weekly mixing**)
- 4 sterile BD Plastipak™ 3 mL Syringes with needle attached (clear cap), for **weekly mixing**
- 33 sterile BD SafetyGlide™ syringes with needle attached (orange cap), for **daily injection**
- 1 box of 100 alcohol swabs

Additional Supplies Required (not provided)

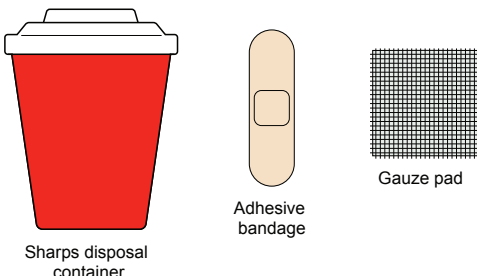


Figure A

Weekly Mixing (Day 1)

Getting Started

For **Weekly Mixing** of EGRIFTA WR, follow steps 1 through 23.

For **Daily Injection** (Day 1 to 7), follow steps 24 through 49.

Step 1: Use a well-lit, clean, and flat surface as a working area.

Step 2: Take out the following: (See **Figure B**)

- One (1) vial of EGRIFTA WR (11.6 mg)
- One (1) 30 mL bottle of Bacteriostatic Water for Injection
- One (1) BD Plastipak™ Syringe with needle attached (clear cap) for **weekly mixing**
- One (1) alcohol swab
- Sharps disposal container

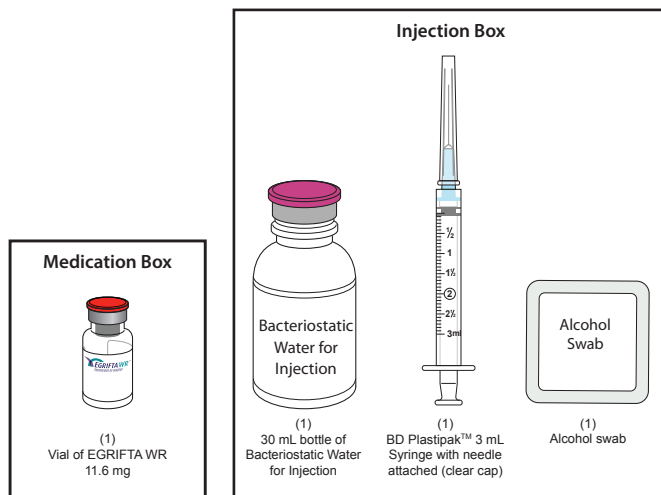


Figure B

Step 3: Wash and dry your hands well. (See **Figure C**)

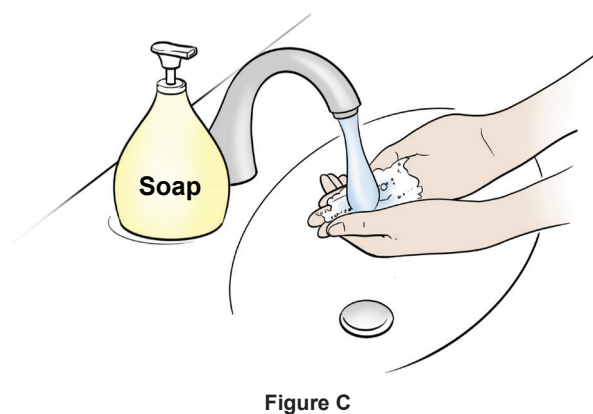


Figure C

Step 4: Inspect the compact powder in the EGRIFTA WR vial. It should be white to off-white. (See **Figure D**)

- Do not use** the vial if the powder is discolored or has particles in it. Get a new vial, and call your healthcare provider, pharmacist, or contact **T: THERA patient support** toll free at 1-833-23THERA (1-833-238-4372).



Figure D

Step 5: Check the expiration dates (**EXP**) on the: (See **Figure E**)

- 1) EGRIFTA WR vial label
- 2) Bacteriostatic Water for Injection bottle

- Do not use** if expired.

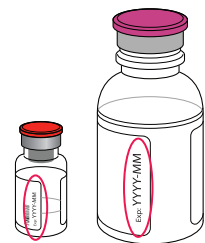


Figure E

Step 6: Remove the plastic caps from the vial and the bottle. (See **Figure F**)

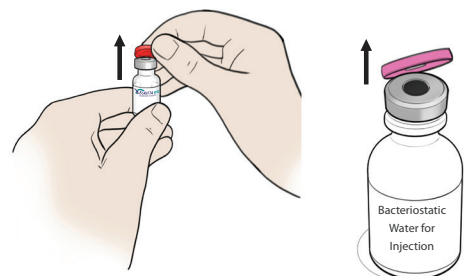


Figure F

Step 7: Clean the top of **both** the vial and the bottle with an alcohol swab (See **Figure G**). Throw away (discard) the alcohol swab after use.

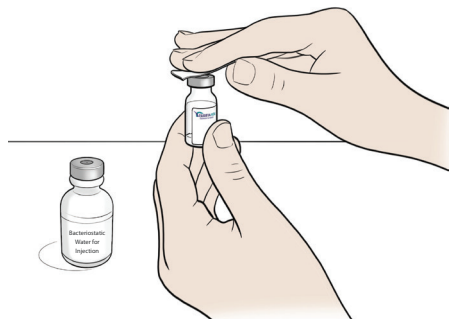


Figure G

Preparing to Mix EGRIFTA WR

Step 8: Take a BD Plastipak™ 3 mL Syringe with needle attached (clear cap) out of its packaging. (See **Figure H**)

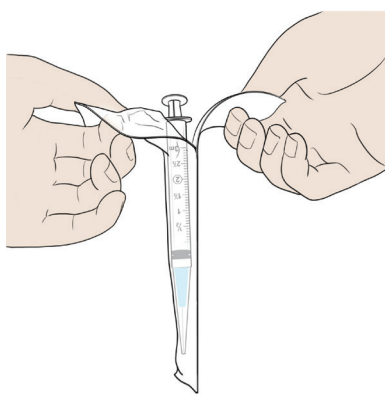


Figure H

Step 9: Pull the protective clear needle cap straight off and throw it away (discard) (See **Figure I**). Make sure the needle is tightly screwed to the syringe.

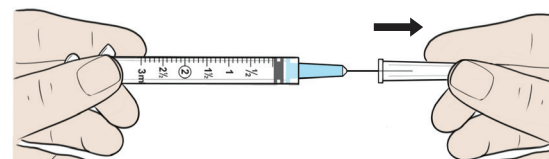


Figure I

Step 10: Pull down the plunger to reach the 1½ mark (1.5 mL) on the syringe to fill it with air. (See **Figure J**)

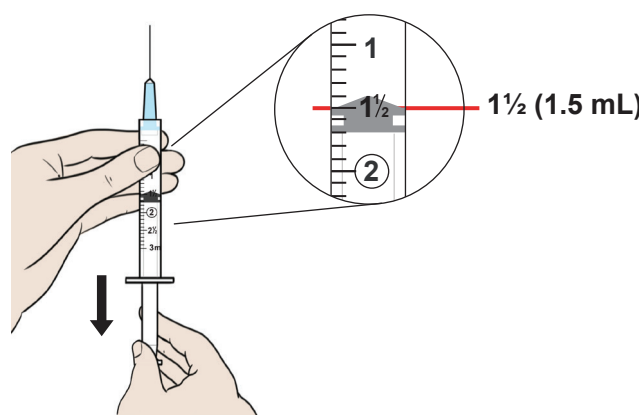


Figure J

Step 11: Insert the needle straight into the top of the Bacteriostatic Water for Injection bottle. (See **Figure K**)

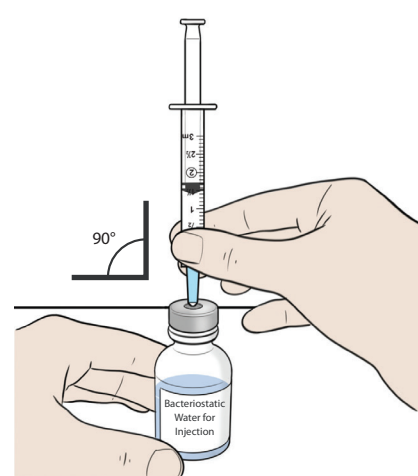


Figure K

Step 12: Turn the bottle and syringe upside down. (See **Figure L**)

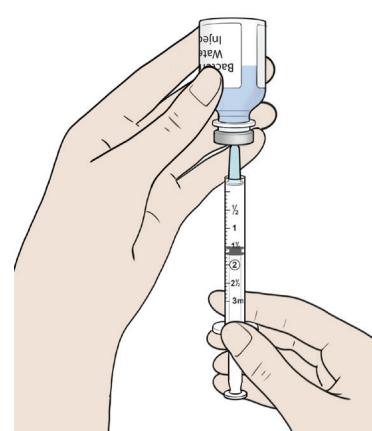


Figure L

Step 13: Push the plunger all the way up (See **Figure M**). Some resistance may be felt.

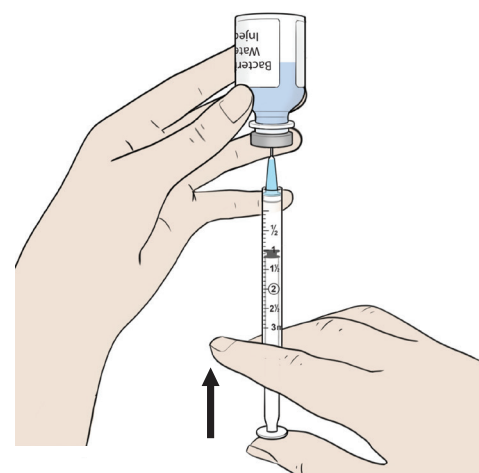


Figure M

Step 14: Pull down the plunger **slowly** to reach the 1½ mark (1.5 mL) on the syringe. A visible air pocket and tiny air bubbles in the syringe are normal. (See **Figure N**)

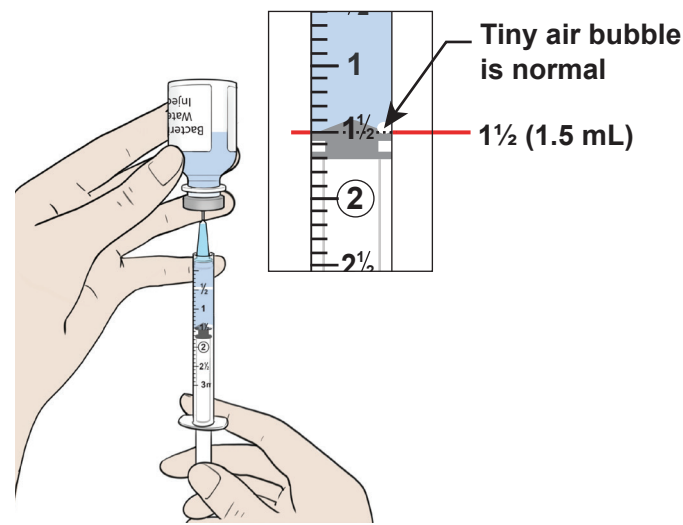


Figure N

Step 15: Turn the bottle right side up and remove the needle. (See **Figure O**)

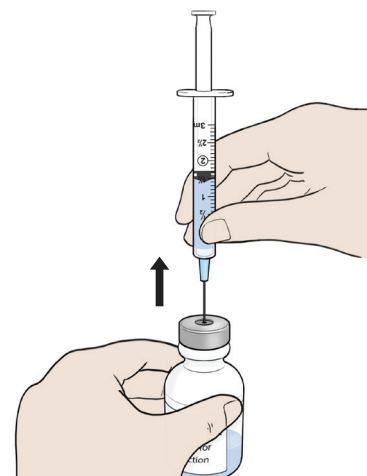


Figure O

Step 16: Place the syringe upright and tap it with your finger to force any large air bubbles to rise to the top. (See **Figure P**)

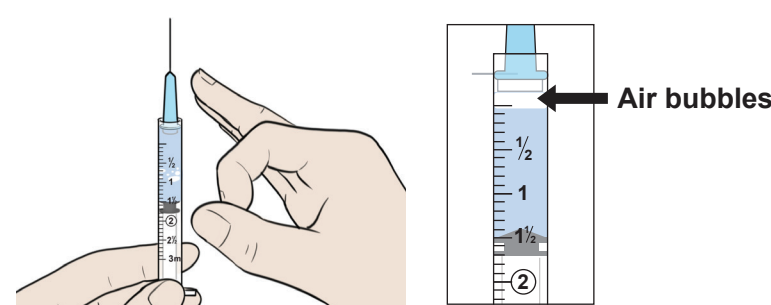


Figure P

Step 17: Push the plunger up **slowly** to remove 0.2 mL of excess water and air out of the syringe and align the **top rim of the plunger** to the 1.3 mL mark. Some water should come out of the needle. (See **Figure Q**)

- If you have **less than 1.3 mL** repeat step 10 to step 17 until 1.3 mL of water is in the syringe.

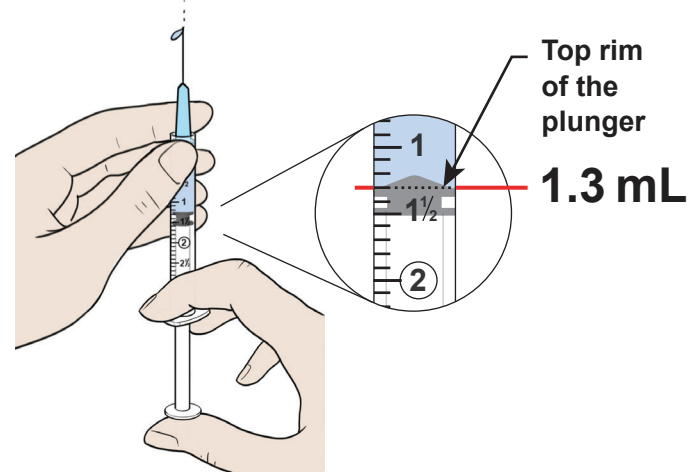


Figure Q

Step 18: Put the Bacteriostatic Water for Injection bottle back in the Injection box for the **next weekly mixing**. (See **Figure R**)

- Throw away (discard) the Bacteriostatic Water for Injection bottle **after 28 days of use**.

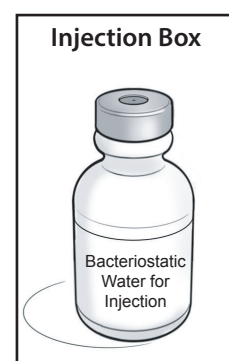


Figure R

Mixing EGRIFTA WR

Step 19: Insert the needle straight into the top of the EGRIFTA WR vial. (See **Figure S**)

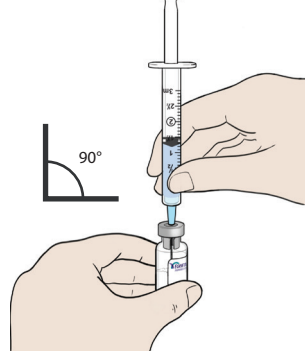


Figure S

Step 20: Push the plunger down until the syringe is completely empty. While keeping the plunger down, remove the needle from the vial. (See **Figure T**)

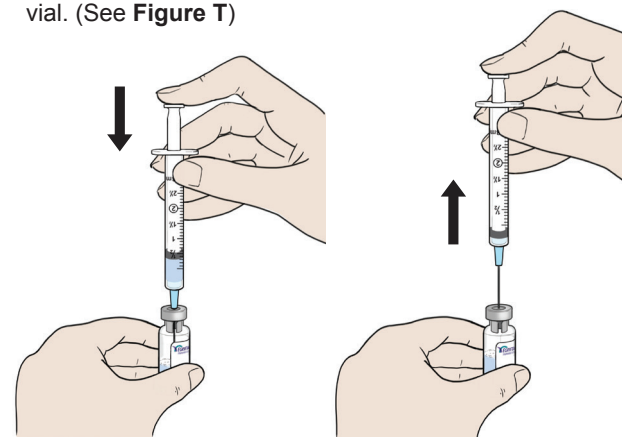


Figure T

Step 21: Throw away (discard) the syringe and needle in the sharps container. (See **Figure U**)



Figure U

Step 22: **Move the vial** in a circle (swirl) to mix all the powder and liquid. (See **Figure V**)

- Do not shake** the vial.

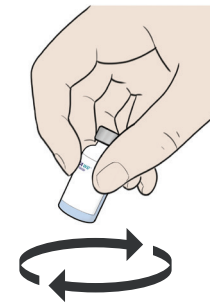


Figure V

Step 23: **Let the vial rest for a few seconds** until the layer of foam separates and the solution becomes clear and colorless, with no particles in it. (See **Figure W**)



Figure W

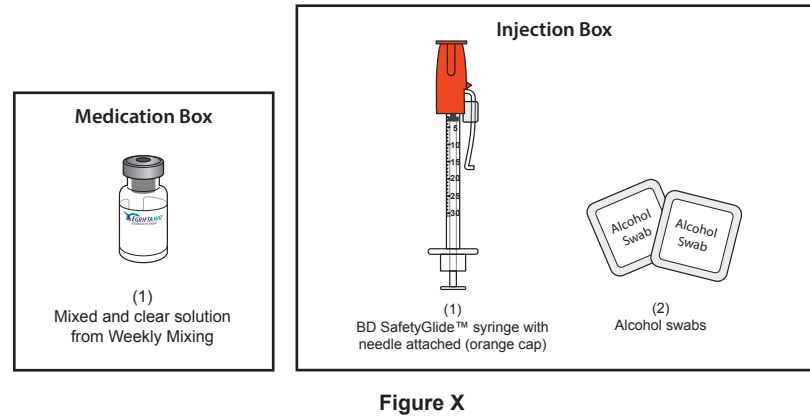
- Do not use** the vial if after a few seconds the solution looks cloudy, is discolored, or has particles in it. Get another vial, and call your healthcare provider, pharmacist, or contact **T: THERA patient support** toll free at 1-833-23THERA (1-833-238-4372).

Daily Injection (Day 1 to Day 7)

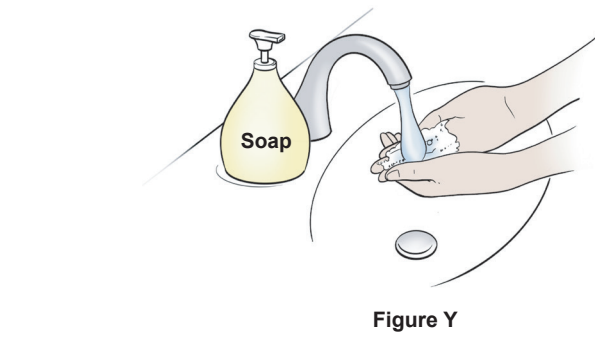
Preparing to Inject EGRIFTA WR

Step 24: For daily injection of EGRIFTA WR (step 24 through step 49), you will need: (See **Figure X**)

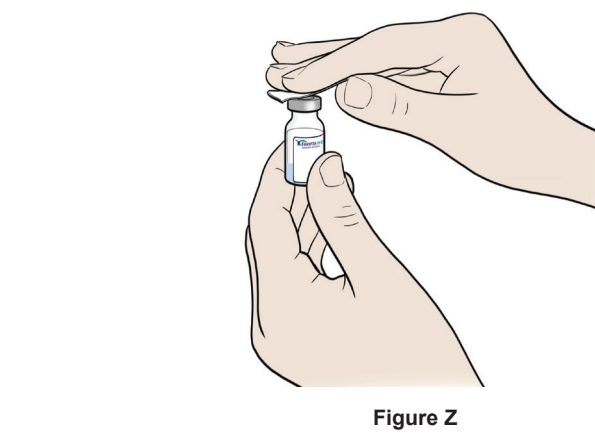
- One (1) **mixed and clear solution** of EGRIFTA WR (**prepared during the weekly mixing**)
- One (1) BD SafetyGlide™ syringe with needle attached (orange cap) for injection
- Two (2) alcohol swabs
- One (1) sterile gauze pad
- One (1) adhesive bandage
- Sharps disposal container



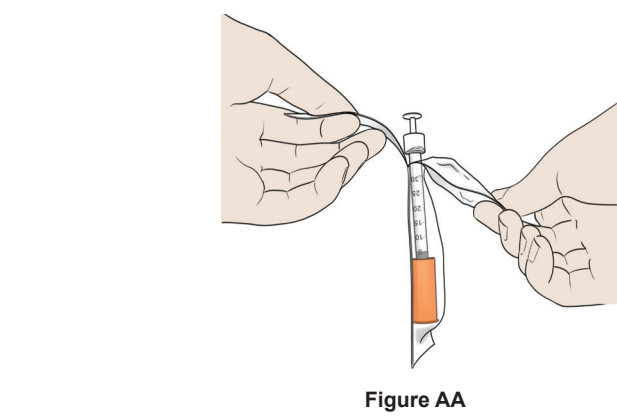
Step 25: Wash and dry your hands well. (See **Figure Y**)



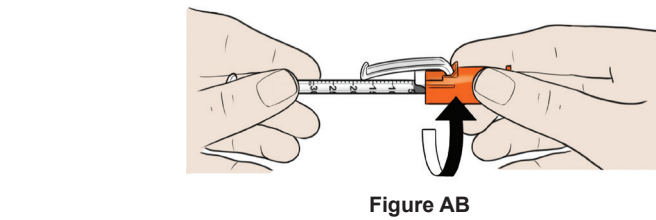
Step 26: Clean the top of the EGRIFTA WR vial with an alcohol swab (See **Figure Z**). Throw away (discard) the alcohol swab after use.



Step 27: Take a BD SafetyGlide™ syringe with needle attached (orange cap) out of its packaging. (See **Figure AA**)

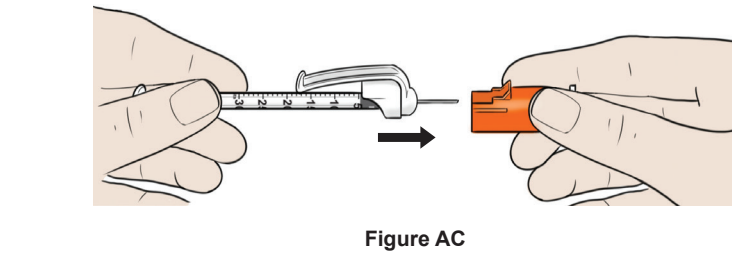


Step 28: Twist the orange needle cap to clearly see the graduated markings on the syringe, if needed. (See **Figure AB**)



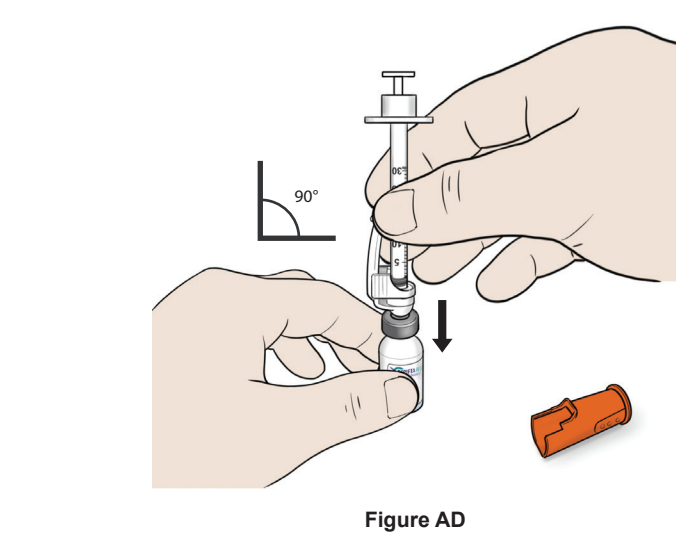
Step 29: Pull the orange needle cap straight off and keep it aside. (See **Figure AC**)

- **Do not** touch the needle.

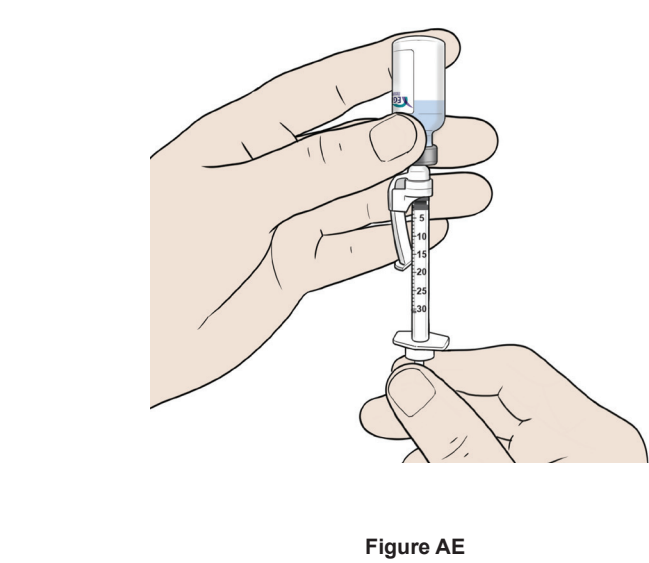


Step 30: Insert the needle carefully and **straight** into the top of the vial to avoid bending the needle. (See **Figure AD**)

- If you bend the needle, use a new syringe.

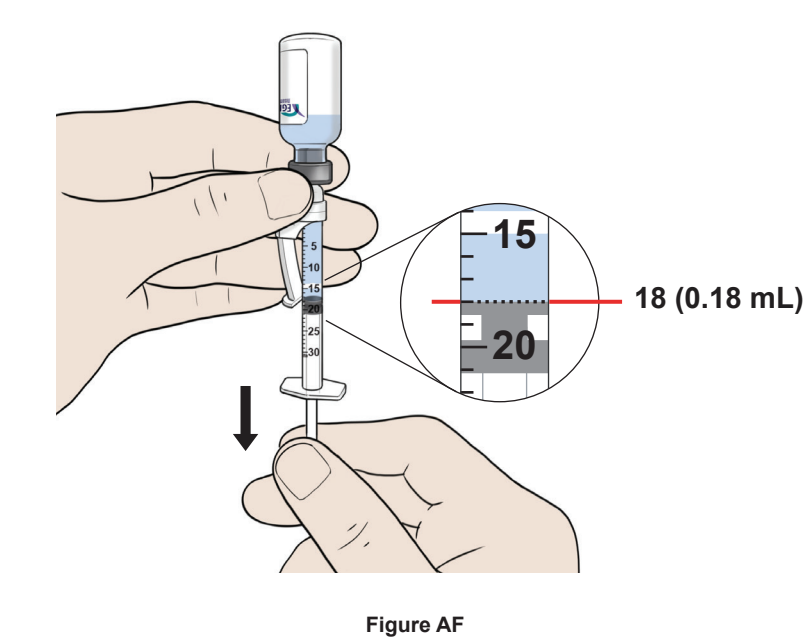


Step 31: Turn the vial and syringe upside down. (See **Figure AE**)

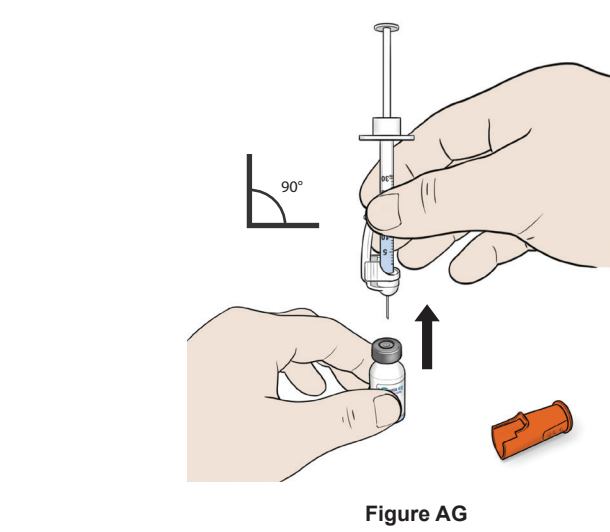


Step 32: Pull down the plunger **slowly** to reach the **18 mark (0.18 mL)**. (See **Figure AF**)

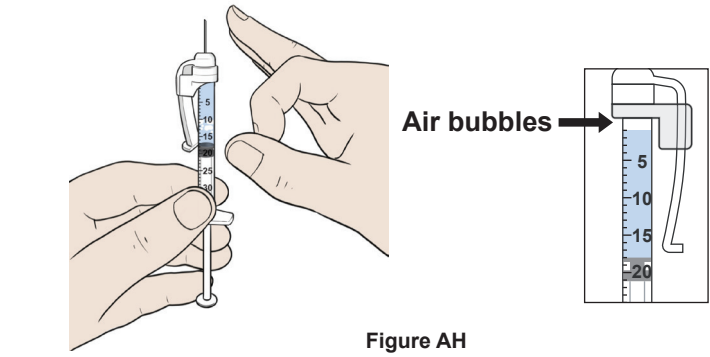
- If you do not have enough liquid in the syringe, **repeat step 30 and step 31**.



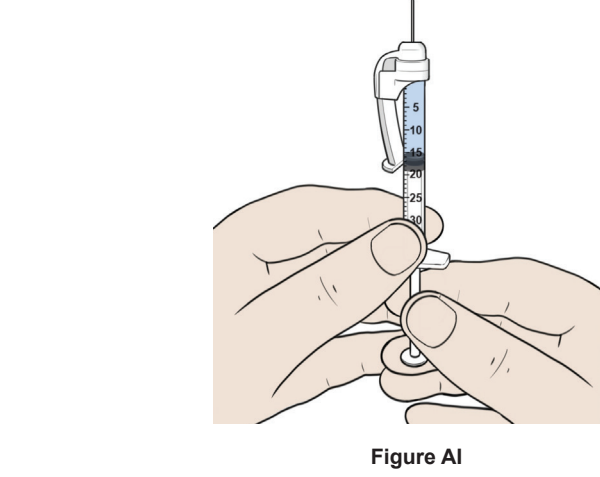
Step 33: Turn the vial right side up and remove the needle. (See **Figure AG**)



Step 34: Place the syringe upright and tap it with your finger to force any air bubbles to rise to the top. (See **Figure AH**)

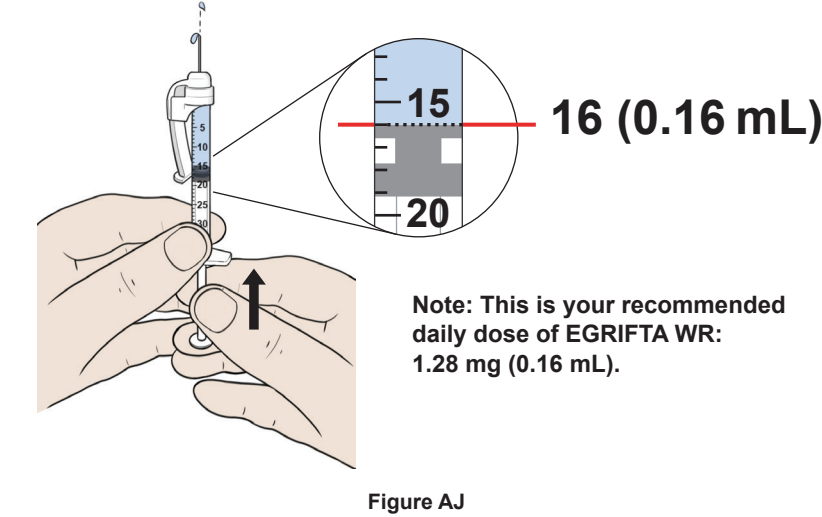


Step 35: Hold the plunger rod half-way to carefully adjust the volume in step 36. (See **Figure AI**)

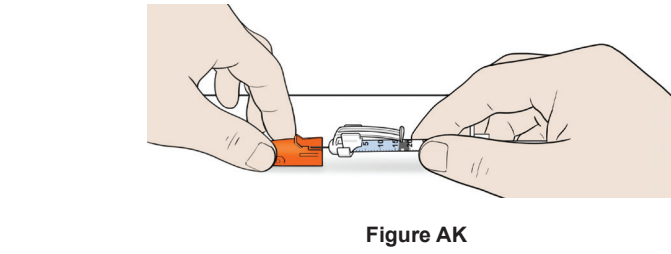


Step 36: Adjust the plunger to reach exactly the **16 mark (0.16 mL)** by slowly pushing the plunger up to remove air and excess liquid from the syringe (See **Figure AJ**). Some resistance may be felt when pushing the plunger.

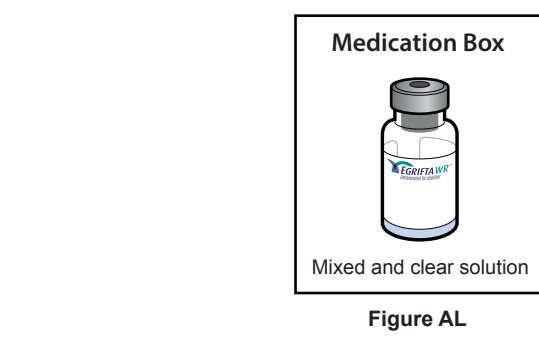
- No air pockets should be left.



Step 37: Safely place the orange needle cap on the needle. (See **Figure AK**)



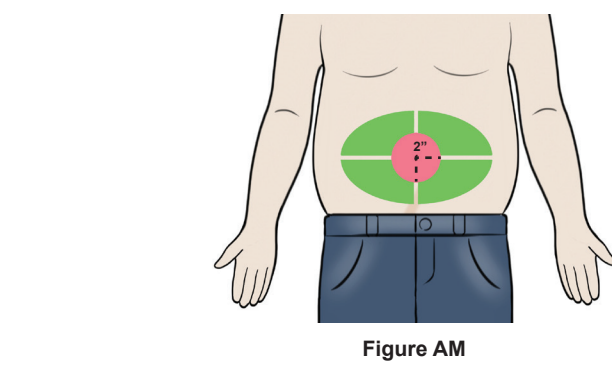
Step 38: Keep the mixed EGRIFTA WR vial for the next **Daily Injections in the Medication Box** at room temperature up to 77°F (25°C). (See **Figure AL**)



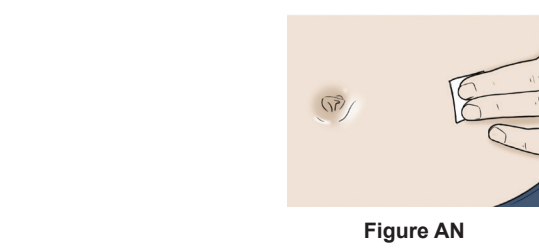
Injecting EGRIFTA WR

Step 39: Choose an **injection site** on the stomach area (abdomen) that is **at least 2 inches (5 cm) away from your belly button**. (See the green area in **Figure AM**)

- **Do not** inject into your belly button, nor on areas with scar tissue, bruises or on any hard bumps from previous injections.
- Rotate the site for each injection. This may help prevent bruising or irritation.

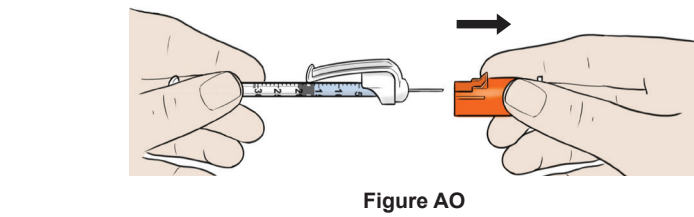


Step 40: Clean the injection site with a **new** alcohol swab and let it dry. (See **Figure AN**)

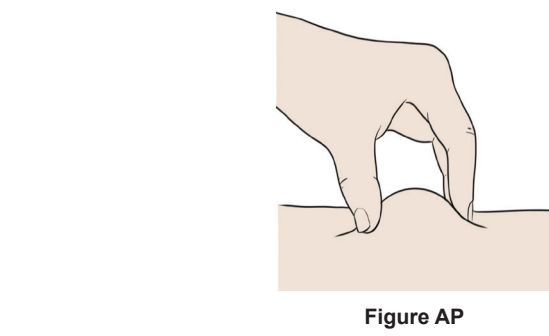


Step 41: Remove the orange needle cap and throw it away (discard). (See **Figure AO**)

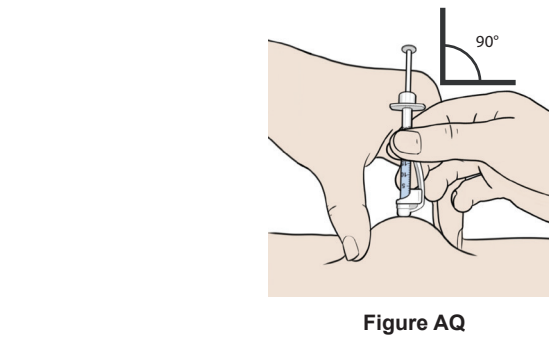
- **Do not** touch the needle.
- **Do not** move the plunger.



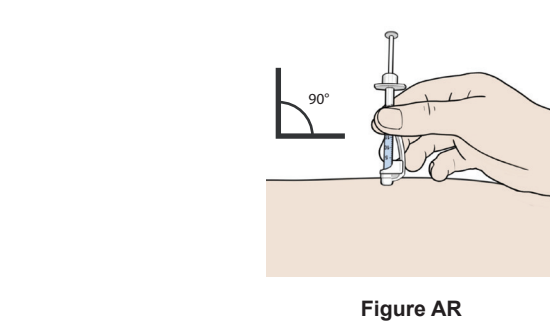
Step 42: Pinch a fold of skin at your cleaned injection site between your thumb and fingers. (See **Figure AP**)



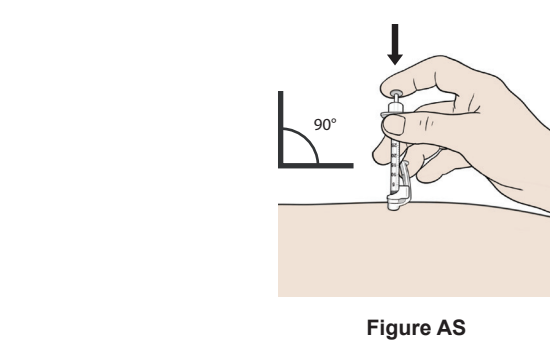
Step 43: Insert the needle straight into the skin. (See **Figure AQ**)



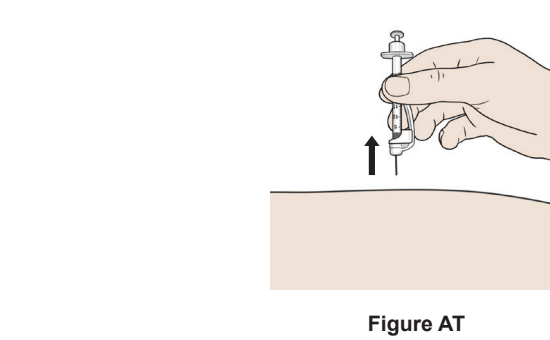
Step 44: Remove your hand from the pinched area of skin, while keeping the needle in the skin. (See **Figure AR**)



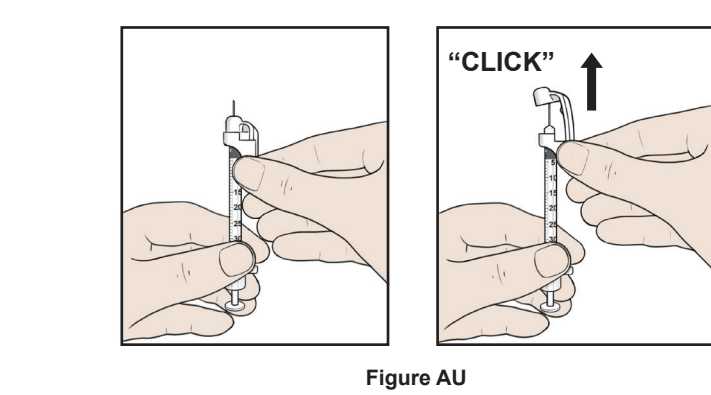
Step 45: Push the plunger all the way down until **all the medicine** in the syringe has been injected under the skin. (See **Figure AS**)



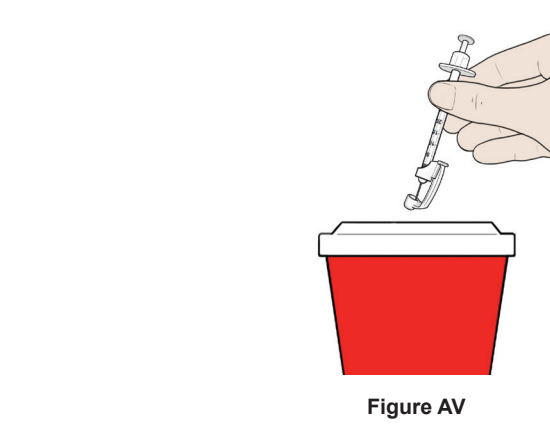
Step 46: Pull the needle out. (See **Figure AT**)



Step 47: Hold the syringe and carefully slide up the white safety needle shield along the needle until you hear a “click”. (See **Figure AU**)



Step 48: Throw away (discard) the syringe with the needle attached into the sharps container. (See **Figure AV**)



Step 49: If there is bleeding at the injection site, use gauze to apply pressure and apply an adhesive bandage if necessary.

For the next Daily Injection (Day 2 to Day 7) go directly to step 24 of this Instructions for Use.

Throw away (discard) the EGRIFTA WR vial after it has been used for 7 Daily Injections (Day 1 to Day 7).

Disposing of EGRIFTA WR

- **Do not recap the needle with the needle cap after you inject EGRIFTA WR.**
- Throw away (discard) the EGRIFTA WR vial after it has been used for **7 Daily Injections (Day 1 to Day 7)**.
- Throw away (discard) the Bacteriostatic Water for Injection bottle after **28 days of use**.
- Put your used EGRIFTA WR needles and syringes in an 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 an 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: <https://www.fda.gov/safesharpsdisposal>.
- **Do not throw away** (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, or you can call **THERA patient support** toll free at 1-833-23THERA (1-833-238-4372) for more information.

Manufactured by: Theratechnologies Inc., 2015 Peel Street, Suite 1100, Montréal, Québec, Canada H3A 1T8

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