



Step-by-Step Administration Guide

Questions about mixing and injecting EGRIFTA WRTM?

THERA patient support® 1-833-238-4372 (1-833-23THERA)

Other questions about EGRIFTA WRTM?

Consult your doctor or pharmacist.

Your healthcare provider has prescribed **EGRIFTA WR™** as a subcutaneous injection—an injection given directly under the skin. You will be given 2 boxes from the pharmacy when you get your prescription of **EGRIFTA WR™**.

- 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].
- The recommended **daily dose of EGRIFTA WR™** is **1.28 mg (0.16 mL)**.
- Store the Medication Box at room temperature at 68–77 °F (20–25 °C) and keep the **EGRIFTA WR™** vials out of the light.
- Store the Injection Box and its contents at room temperature at 68–77 °F (20–25 °C).
- There are two **EGRIFTA** formulations (**EGRIFTA WR™** and **EGRIFTA SV®**) with different recommended dosages. **EGRIFTA WR™** and **EGRIFTA SV®** are not substitutable.

IMPORTANT SAFETY INFORMATION

What is **EGRIFTA WR™** (tesamorelin) for injection?

- **EGRIFTA WR™** is a prescription medicine used to reduce the excess stomach-area (abdominal) fat in adults with HIV and lipodystrophy.
- **EGRIFTA WR™** is a growth hormone-releasing factor (GHRF) analog.
- **EGRIFTA WR™** is not for weight loss management.
- The long-term safety of **EGRIFTA WR™** on the heart and blood vessels (cardiovascular) is not known.
- It is not known whether taking **EGRIFTA WR™** helps improve how well you take your antiretroviral medications.
- It is not known if **EGRIFTA WR™** is safe and effective in children; do not use **EGRIFTA WR™** in children.

You should not use **EGRIFTA WR™** if you:

- Have a pituitary gland tumor, surgery, or other problems related to your pituitary gland, or have had radiation treatment to your head or a head injury.
- Have active cancer.
- Are allergic to tesamorelin or any of the ingredients in **EGRIFTA WR™**.
- Are pregnant or become pregnant. If you become pregnant, stop using **EGRIFTA WR™** and talk with your healthcare provider.
- Are less than 18 years of age.

Before using **EGRIFTA WR™**, tell your healthcare provider about all of your medical conditions, including if you:

- Have or have had cancer.
- Have problems with blood sugar or diabetes.
- Have scheduled heart or stomach surgery.
- Have breathing problems.
- Are breastfeeding or plan to breastfeed.
- Are taking any other prescription and non-prescription medicines, vitamins, and herbal supplements.

EGRIFTA WR™ may cause serious side effects including:

- **Increased risk of new cancer in adults with HIV or your cancer coming back (reactivation).** Stop using EGRIFTA WR™ and inform your healthcare provider 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 WR™.
- **Serious allergic reaction** such as rash or hives anywhere over the body or on the skin, swelling of the face or throat, shortness of breath or trouble breathing, fast heartbeat, feeling of faintness or fainting, itching and reddening or flushing of the skin. **If you have any of these symptoms, stop using EGRIFTA WR™ and get emergency medical help right away.**
- **Swelling or fluid retention.** Call your healthcare provider if you have swelling, an increase in joint pain, or pain or numbness in your hands or wrists.
- **Increase in blood sugar (glucose) or diabetes.**
- **Injection site reactions.** Injection site reactions are a common side effect of EGRIFTA WR™ but may sometimes be serious.
- **Increased risk of death in people who have critical illness because of heart or stomach surgery, trauma or serious breathing (respiratory) problems** has been reported after treatment with therapeutic doses of growth hormone.

The most common side effects of EGRIFTA WR™ include:

- Pain in legs and arms
- Muscle pain

These are not all the possible side effects of **EGRIFTA WR™**. 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).

This information is not intended to replace discussions with your doctor.

For additional information about EGRIFTA WR™, go to: www.egriftawr.com for the Patient Information and Patient Instructions for Use, and talk to your doctor. For more information about EGRIFTA WR™ contact THERA patient support® toll-free at 1-833-23THERA (1-833-238-4372).

Important Information for the use of EGRIFTA WR™

- **Do not share your EGRIFTA WR™ vials, syringes, 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.**
- **Do not use a syringe or needle more than one (1) time.**

Step by Step Guide

Before You Start

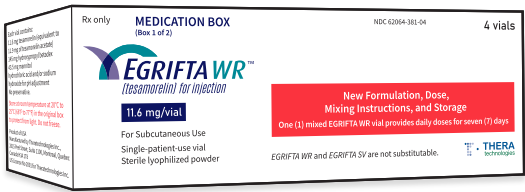
Find a well-lit, clean, and flat surface, such as a table. Gather your supplies.
Make sure you have two boxes, the Medication Box and the Injection Box.

Open the two boxes and make sure all the materials listed below are there. If you are missing any supplies described below or if they look damaged or expired, call your pharmacist or **THERA patient support®** at 1-833-238-4372 (1-833-23THERA).

Each box should contain supplies for 28 days.

HELPFUL TIP

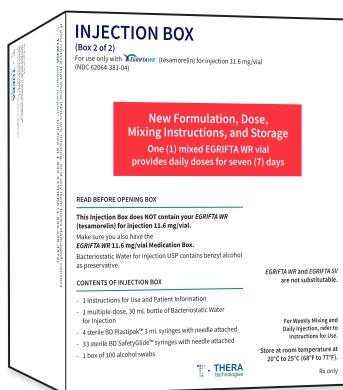
Set up a daily injection reminder, unless otherwise instructed by your healthcare provider.



Medication Box

Quantity	Item
4	Single-patient use EGRIFTA WR™ 11.6 mg vials (mix only 1 vial per week as per weekly mixing)

Do not use EGRIFTA WR™ if the expiration date on the side of the Medication Box has passed.



Injection Box

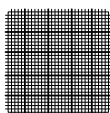
Quantity	Item
1	Multiple-dose, 30 mL bottle of Bacteriostatic Water for Injection (to be used for weekly mixing)
4	Sterile BD Plastipak™ 3 mL Syringes with needle attached (clear cap) (for weekly mixing)
33	Sterile BD SafetyGlide™ syringes with needle attached (orange cap) (for daily injection)
1	Box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



Sharps disposal
Container



Adhesive
bandage



Gauze pad

Additional Supplies Required (not provided)

- Adhesive bandage
- Gauze pad
- Sharps disposal container or a puncture resistant container for throwing away used needs and syringes after you are done with them.

Never throw used needles, syringes, or sharps containers in your household trash. If you accidentally prick another person with a needle, immediately report the incident to a healthcare provider. Keep the sharps container away from children and pets. **Make sure to keep your hands and work area clean at all times.**

Weekly Mixing (Day 1)

Getting Ready



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

From the **Medication Box**, take out one (1)
vial of *EGRIFTA WR*TM 11.6 mg



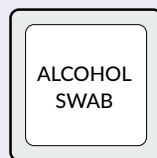
From the **Injection Box**, take out:



One (1) 30 mL bottle
of Bacteriostatic
Water for Injection



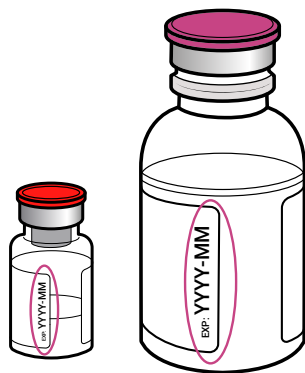
One (1) BD PlastipakTM 3 mL
Syringe with needle attached
(clear cap) **weekly mixing**




One (1)
Alcohol Swab

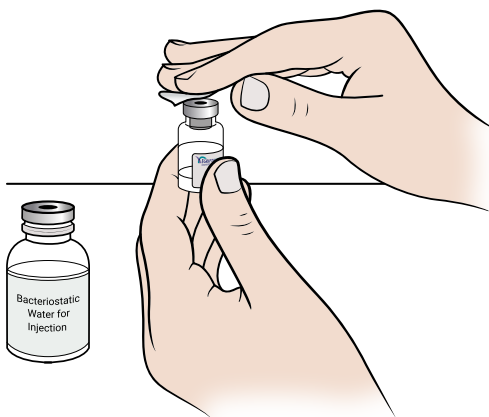
Have your sharps disposal container ready.

- Check the **expiration dates (EXP)** on the *EGRIFTA WR™* vial label and the Bacteriostatic Water for Injection **bottle**. **Do not** use if expired.
- Inspect the compact powder in your *EGRIFTA WR™* vial. It should be **white to off-white**.



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  **• THERA patient support** toll free at 1-833-23THERA (1-833-238-4372).

- Remove the plastic caps from the **vial** and the **bottle**.
- Clean the top of **both** the vial and the bottle with an alcohol swab. Throw the alcohol swab away after use.

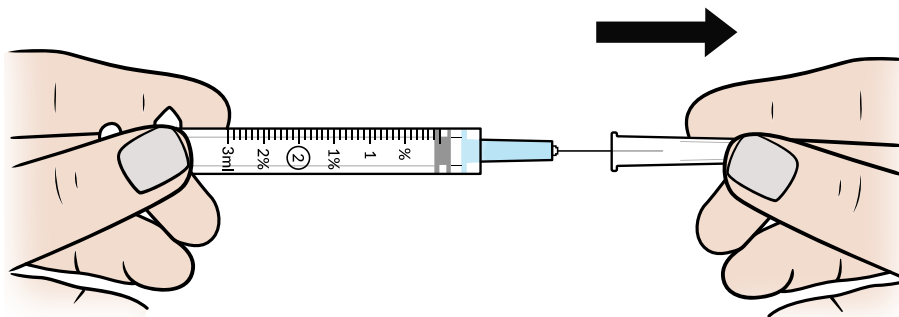


Weekly Mixing (Day 1)

Preparing to Mix *EGRIFTA* WR™

1

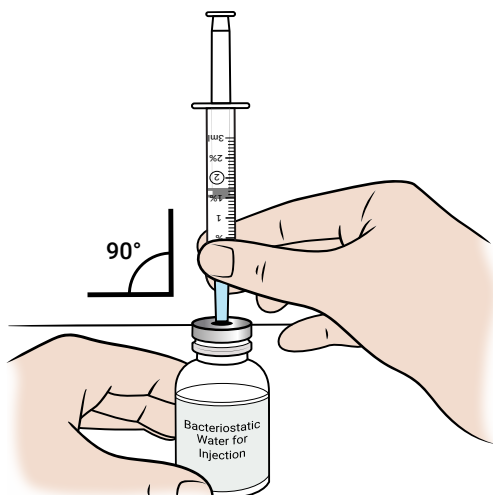
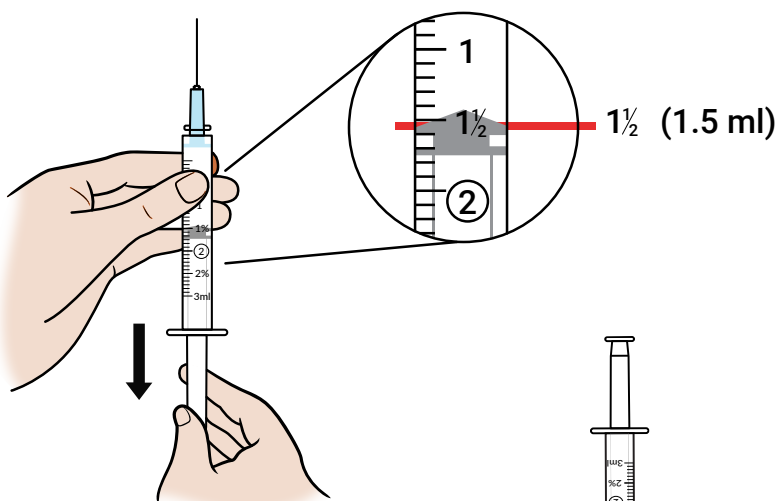
Take the BD Plastipak™ 3 mL Syringe with needle attached (clear cap) out of its packaging. Make sure the needle is screwed on tightly to the syringe. Pull the protective clear needle cap straight off and throw it away (discard).



Do not twist the needle cap when taking it off.

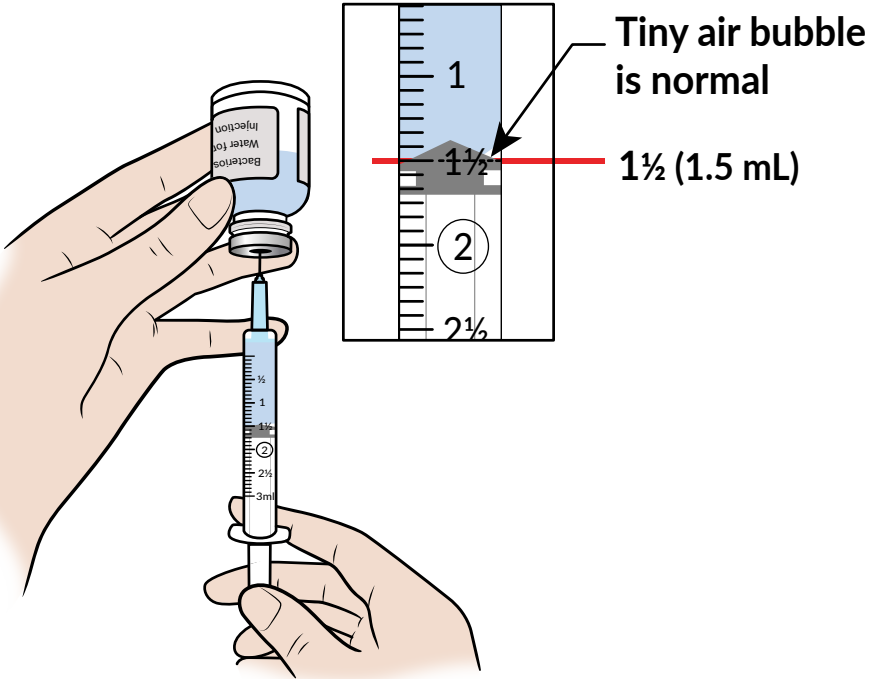
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Pull down the plunger to reach the **1½ mark (1.5 mL)** on the syringe to fill it with air. Insert the needle straight into the top of the Bacteriostatic Water for Injection bottle.



3

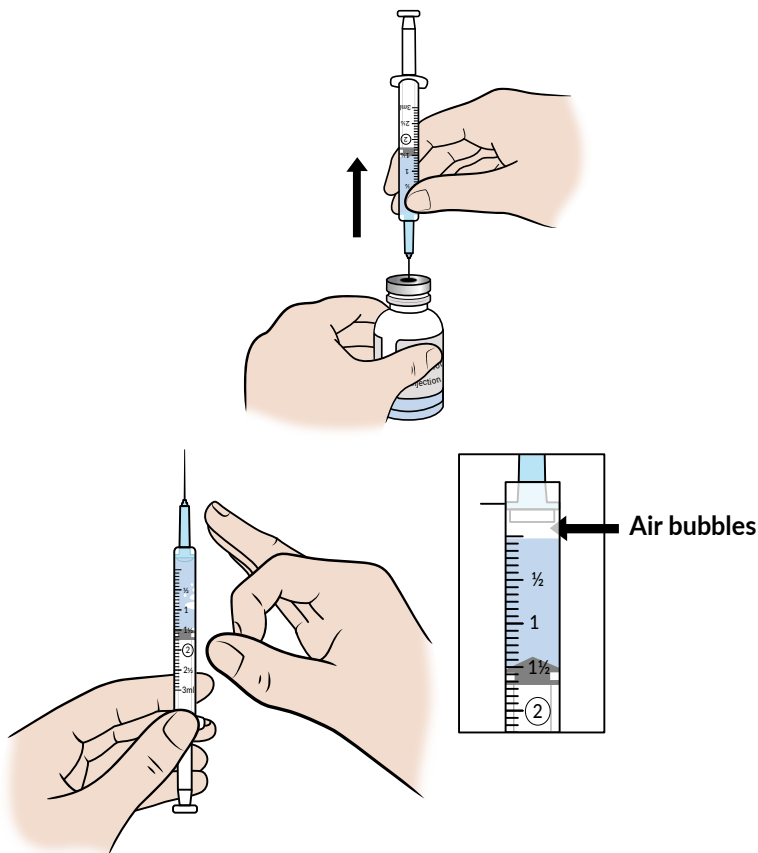
Turn the bottle and syringe upside down. Push the plunger all the way up. Some resistance may be felt. Then, pull the plunger down **slowly** to reach the **1½ mark (1.5 mL)** on the syringe.



It is normal to see a visible air pocket and tiny air bubbles in the syringe.

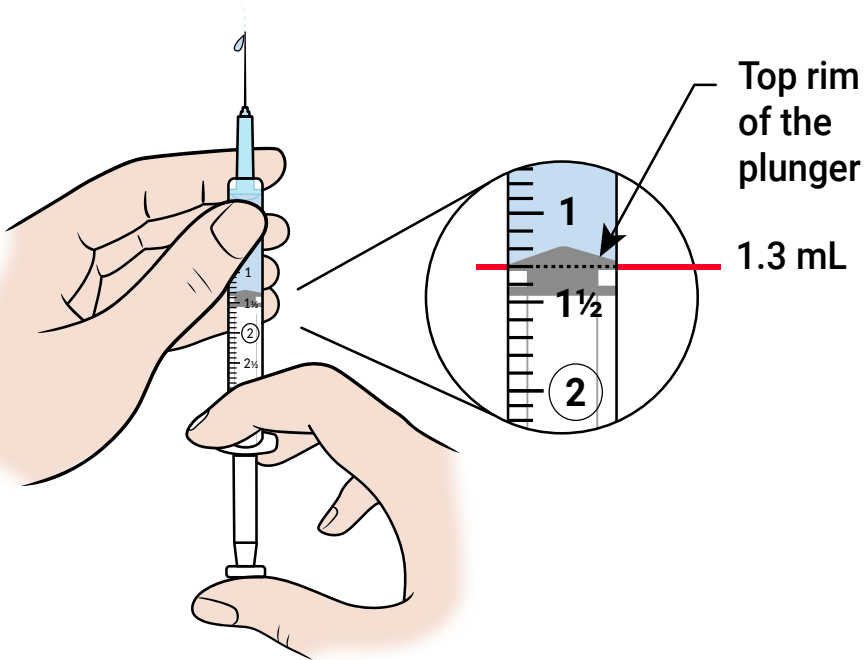
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Turn the bottle right side up and pull out the needle. Set the bottle down. Hold the syringe with needle pointing up and tap it with your finger to force any large air bubbles to rise to the top.



5

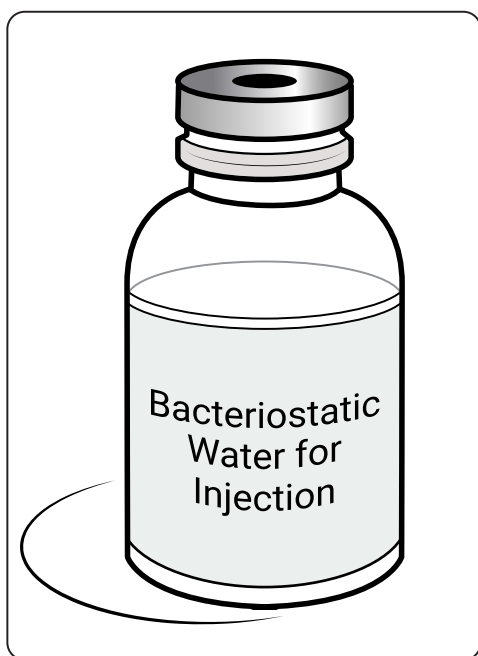
Slowly push the plunger up to remove 0.2 mL of excess water and air from the syringe. Make sure the **top rim of the plunger** is at the **1.3 mL** mark. Some water should come out of the needle.



If you have less than 1.3 mL repeat steps 3 to 5 until 1.3 mL of water is in the syringe.

6

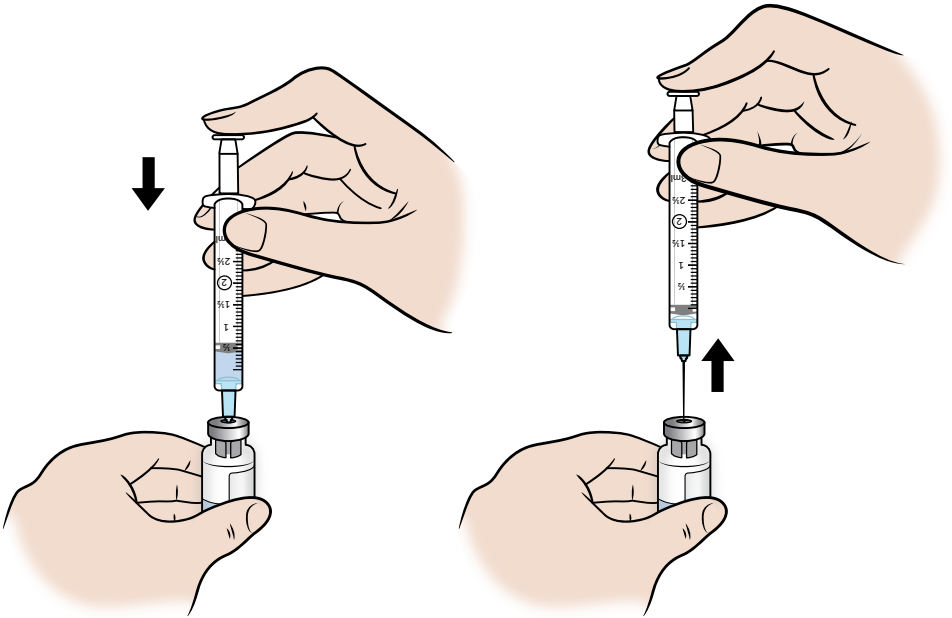
Put the Bacteriostatic Water for Injection bottle back in the Injection box for the **next weekly mixing**.



Throw away the Bacteriostatic Water for Injection bottle after 28 days of use. Record the date of first use of the Bacteriostatic Water for Injection bottle as indicated on the back side of the Injection Box. The mixing and injection tracker provided inside the injection box can also be used to record this information.

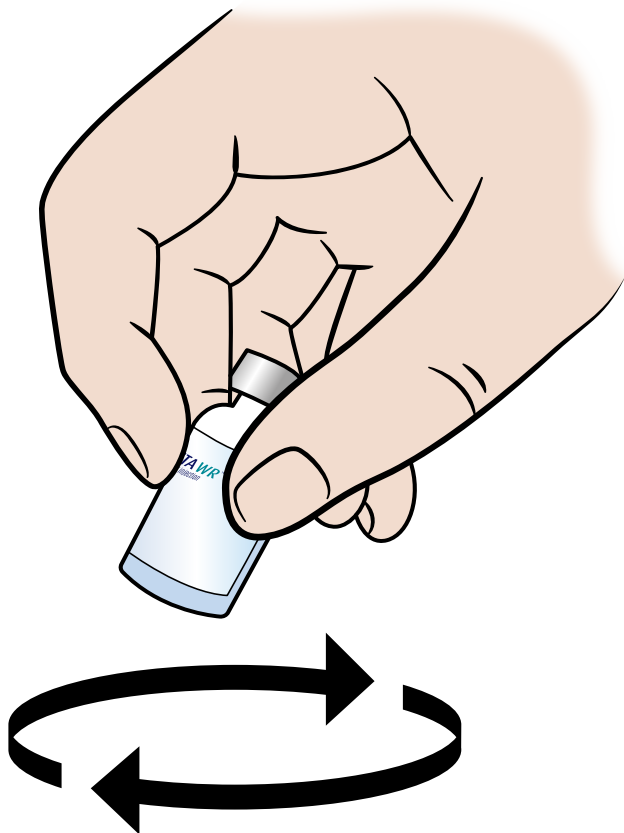
7

Insert the needle straight into the top of the **EGRIFTA WR™ vial**. Push the plunger down until the syringe is completely empty. While the plunger is down, remove the needle from the vial.



8

Throw away the syringe and needle in the sharps container. **Move the vial** in a circle (swirl) to mix all the powder and liquid.



Do not shake the vial.

9


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.



Layer of foam

Clear solution

ready to be used

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  **THERA** patient support[®] toll free at 1-833-23THERA (1-833-238-4372).

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Daily Injection (Day 1 to Day 7)

Getting Started



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

You will need one (1) **mixed and clear solution** of EGRIFTA WR™ (prepared during the weekly mixing)



From the Injection Box, take out:



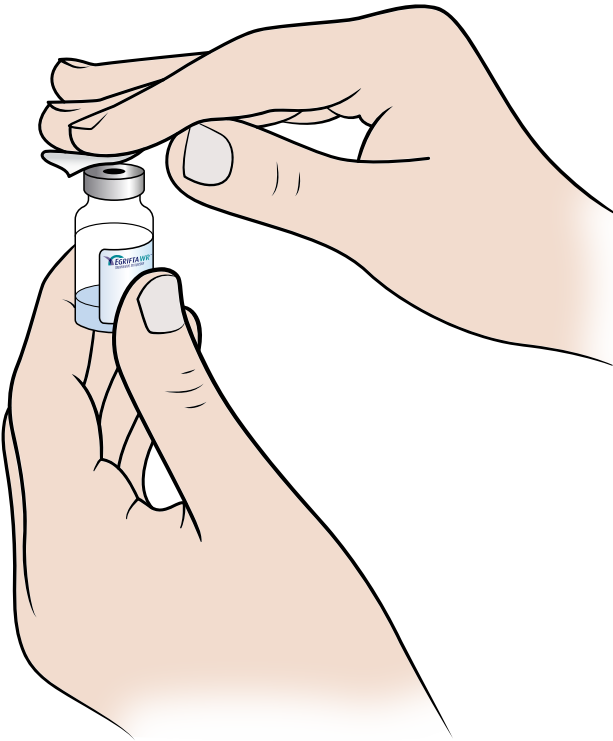
One (1) BD SafetyGlide™
Syringe with Needle Attached
(orange cap)



Two (2)
Alcohol Swabs

Have your sharps disposal container ready.

Clean the top of the *EGRIFTA WR*TM vial with an alcohol swab.
Throw away the alcohol swab after use.



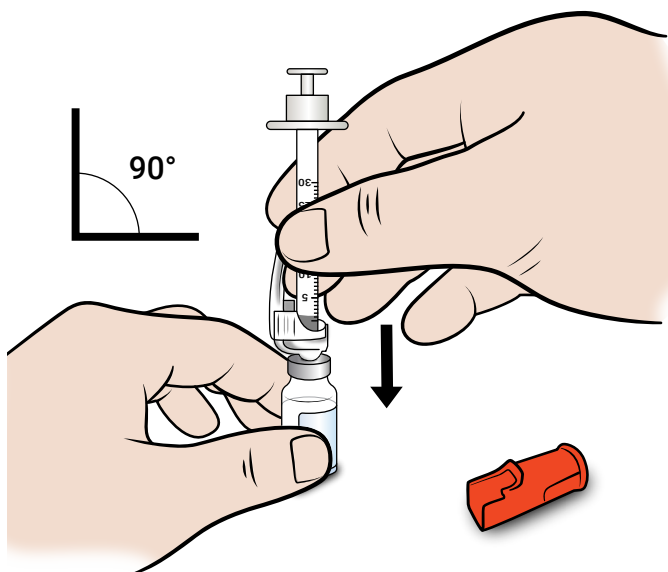
Daily Injection (Day 1 to Day 7)

Preparing to Inject *EGRIFTA WR*TM

1

Take a BD SafetyGlideTM syringe with needle attached (orange cap) out of its packaging. Twist the orange needle cap to clearly see the graduated markings on the syringe, if needed. Pull the orange needle cap straight off and keep it aside.

Insert the needle carefully and **straight** into the top of the vial to avoid bending the needle.



If you bend the needle, use a new syringe.

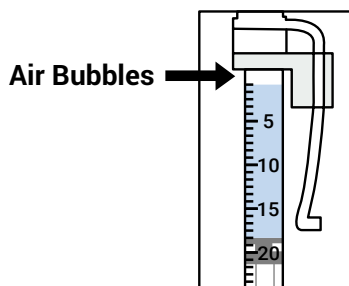
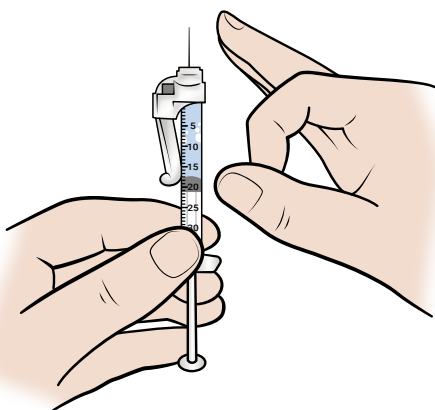
Do not touch the needle.

2

Turn the vial and syringe upside down. Pull down the plunger **slowly** to reach the **18 mark (0.18 mL)**.

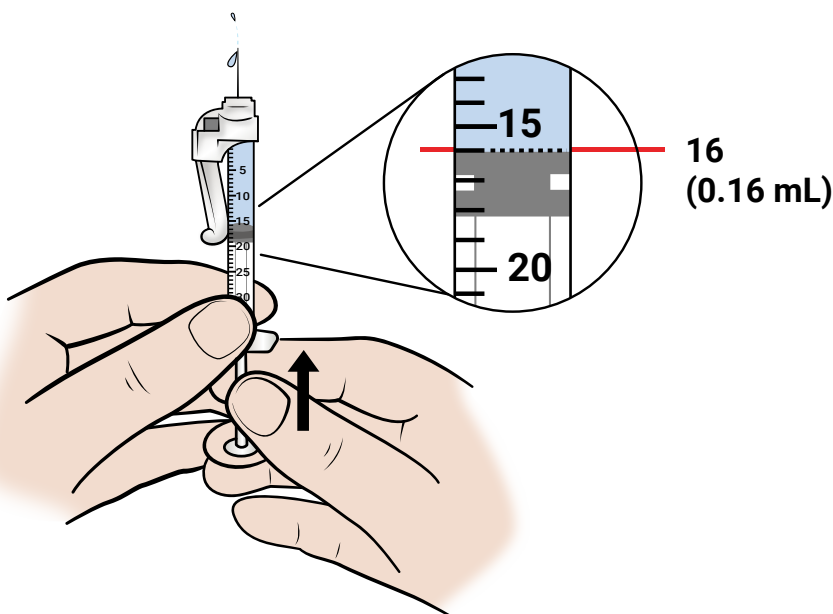
If you do not have enough liquid in the syringe, **repeat the previous step**.

Turn the vial right side up and remove the needle. Hold the syringe upright and tap it with your finger to force any air bubbles to rise to the top.



3

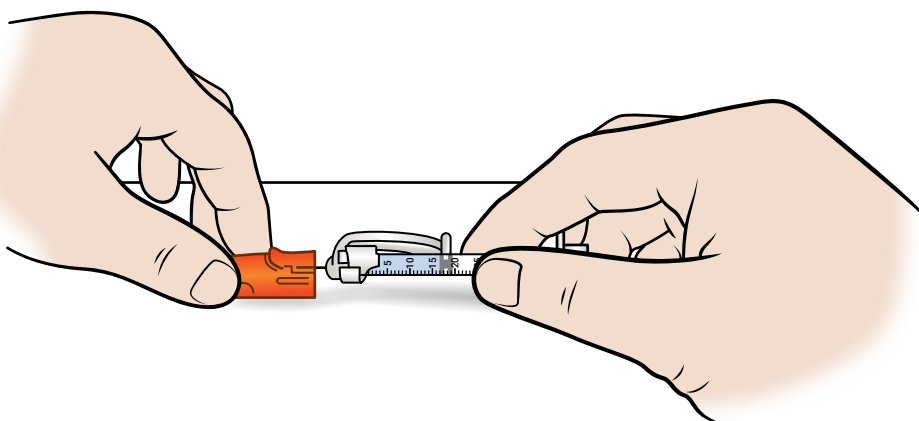
Hold the plunger rod half-way to carefully adjust the volume. Adjust the plunger to reach exactly the **16 mark (0.16 mL)** by slowly pushing the plunger up to remove air and excess liquid from the syringe. You may feel some resistance when pushing the plunger. No air pockets should be left.



**This is your recommended daily dose
of EGRIFTA WR™: 1.28 mg (0.16 mL)**

4

Safely place the orange needle cap on the needle.



HELPFUL TIP

Store the mixed *EGRIFTA* WR™ **vial for the next Daily Injection(s)** in the **Medication Box** at room temperature up to 77°F (25°C). Throw away (discard) the *EGRIFTA* WR™ vial after it has been used for **7 Daily Injections (Day 1 to Day 7)**.

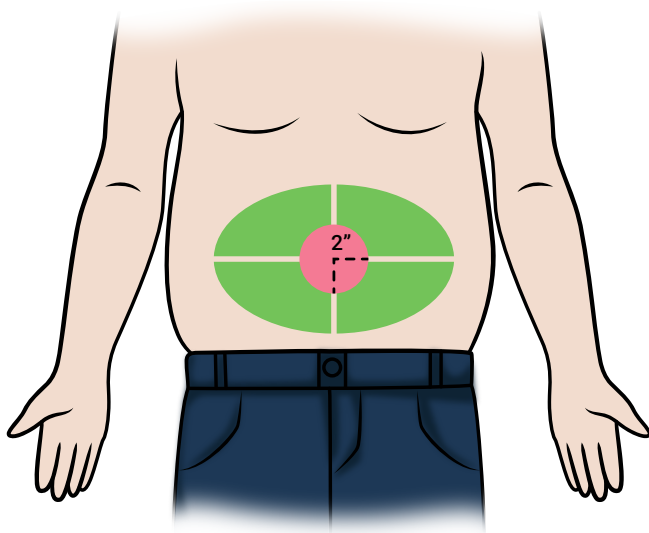
Daily Injection (Day 1 to Day 7)

Injecting *EGRIFTA WR*[™]

1

Inject *EGRIFTA WR*[™] into the abdomen (belly).

- Choose an **injection site** that is **at least 2 inches (5 cm) away from your belly button**.
- **Do not** inject into your belly button or areas with scars or bruises.
- Avoid areas with hard bumps from previous injections.

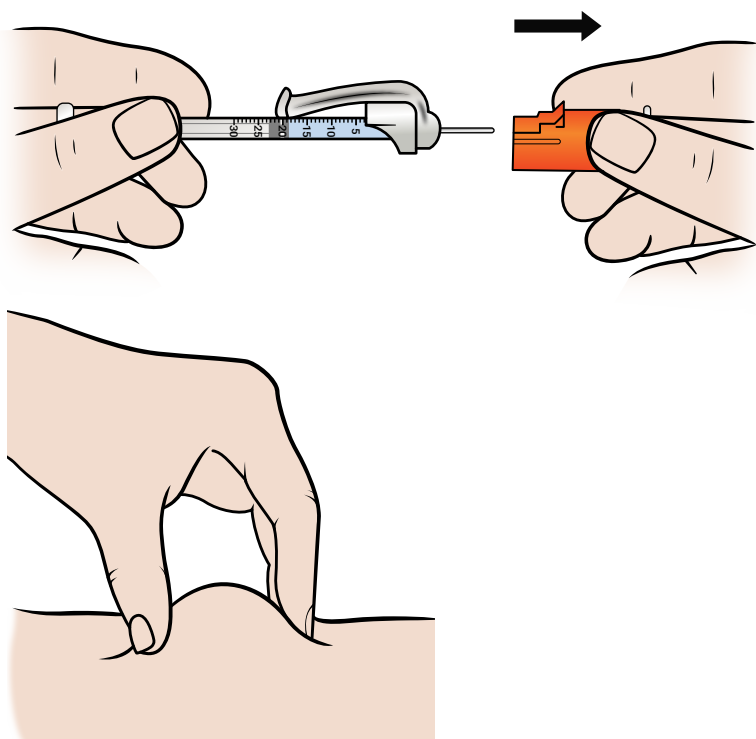


HELPFUL TIP

Rotate the site for each injection to help prevent bruising or irritation. Write down the date and location of each daily injection to help you remember.

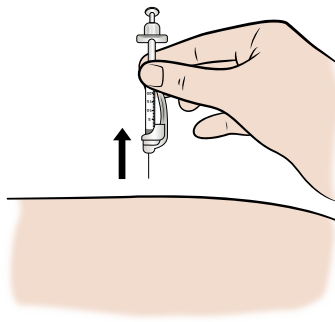
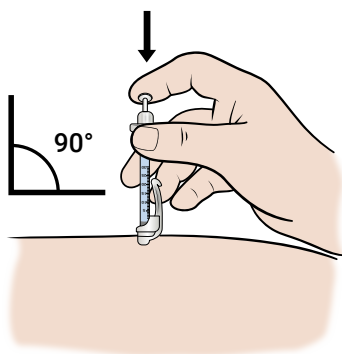
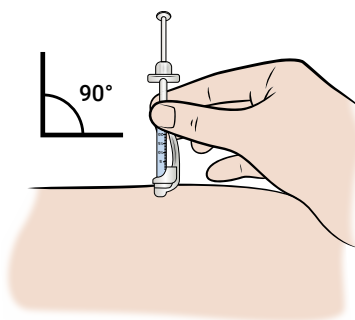
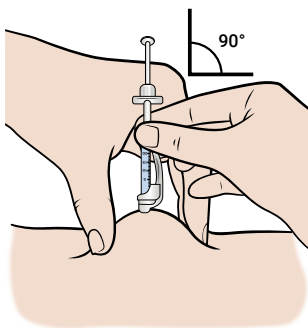
2

- Clean the injection site with a **new** alcohol swab and let it dry.
- Remove the orange needle cap and throw it away (discard).
 - **Do not** touch the needle
 - **Do not** move the plunger
- Holding the syringe in one hand, with your other hand gently pinch a fold of skin between your thumb and fingers at the cleaned injection site.



3

- Insert the needle straight into the skin.
- Remove your hand from the pinched area of skin, while keeping the needle in the skin.
- Push the plunger all the way down until **all the medicine** in the syringe has been injected under the skin.
- Pull the needle out at the same angle as it was inserted.

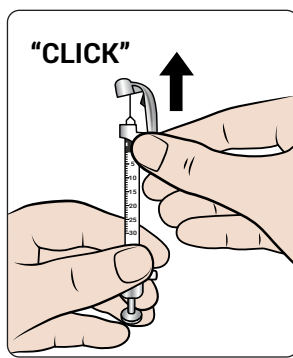
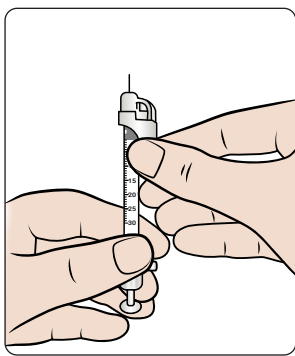


Daily Injection (Day 1 to Day 7)

Finishing Up

4

Hold the syringe and carefully slide up the white safety needle shield along the needle until you hear a “click”.



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

5

If there is bleeding at the injection site, use gauze to apply pressure and apply an adhesive bandage if necessary. Throw away the syringe with the needle attached into the sharps container.




Daily Injection (Day 1 to Day 7)

Disposing of *EGRIFTA* WR™

- **Do not** recap the needle or remove the needle from the syringe 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 (discard) away 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 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
 - 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: 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, contact a healthcare provider right away.
- Keep the sharps container away from children and pets.

If you have any questions

You can call  • **THERA** patient support[®] toll free at 1-833-23THERA (1-833-238-4372) for more information.

Please see page 2 for Important Risk and Safety Information and also at www.egriftawr.com.

Notes:

Notes:



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

