



STEP-BY-STEP ADMINISTRATION GUIDE

Questions about mixing and injecting *EGRIFTA SV*[®]?

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

www.EGRIFTASV.com

Other questions about *EGRIFTA SV*[®]?

Consult your doctor or pharmacist.

Your healthcare provider has prescribed *EGRIFTA SV*® 2 mg as a subcutaneous injection – an injection given under the skin, not into the muscle. You will be given 2 boxes from the pharmacy when you get your prescription of *EGRIFTA SV*®:

- Store the *EGRIFTA SV*® vials in the **Medication Box** they come in, at room temperature between 68°F to 77°F (20°C to 25°C); keep the vials out of the light.
- 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).

IMPORTANT RISK INFORMATION

What is *EGRIFTA SV*® (tesamorelin for injection)?

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

You should not take *EGRIFTA SV*® 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 head injury.
- Have active cancer.
- Are allergic to tesamorelin or any of the ingredients in *EGRIFTA SV*®.
- Are pregnant or become pregnant. If you become pregnant, stop using *EGRIFTA SV*® and talk with your healthcare provider.
- Are less than 18 years of age.

Before using *EGRIFTA SV*®, tell your healthcare provider 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 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*®.
- **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 SV*® 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 wrist.
- **Increase in blood sugar (glucose) or diabetes**
- **Injection-site reactions.** Injection-site reactions are a common side effect of *EGRIFTA SV*®, 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 happened when taking certain growth hormones.

The most common side effects of *EGRIFTA SV*® include:

- Pain in legs and arms
- Muscle pain

These are not all of 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 or to **THERA patient support**® toll-free at 1-833-23-THERA (1-833-238-4372).

This information is not intended to replace discussions with your doctor. For additional information about *EGRIFTA SV*®, go to: <http://egriftasv.com> for the full Prescribing Information, Patient Information and Patient Instructions for Use, and talk to your doctor. For more information about *EGRIFTA SV*® contact **THERA patient support**® toll-free at 1-833-23-THERA (1-833-238-4372).

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.**

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, call your pharmacist or **THERA patient support**® at 1-833-238-4372 (1-833-23-THERA).

The boxes should contain:

MEDICATION BOX	
Quantity	Item
30	EGRIFTA SV® 2 mg single-dose vials in powder form

INJECTION BOX	
Quantity	Item
30	Single-dose 10 mL bottles of Sterile Water for Injection (for mixing)
60	Sterile 1 mL syringes
60	Sterile 1" 20-gauge needles (for mixing)
30	Sterile ½" 30-gauge needle (for injection)



Other supplies you will need for each injection:

- 2 alcohol pads
- 1 sterile gauze
- 1 adhesive bandage
- Sharps disposal container or a puncture-resistant container for throwing away used needles and syringes after you are done with them.



EGRIFTA SV® must be injected in the dosage amount that your healthcare provider prescribed, ideally at the same time every day.

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

HELPFUL TIP

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

Never reuse or recycle needles or syringes. Never throw used needles, syringes, or sharps containers into the 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.**

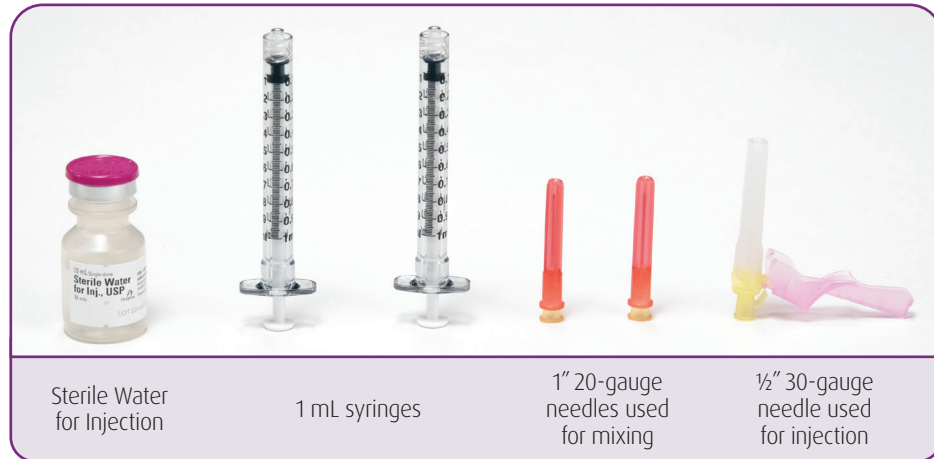
GETTING READY

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

From the Medication Box,
take out **1 vial** of **EGRIFTA SV®**:



From the Injection Box, take out:



Sterile Water
for Injection

1 mL syringes

1" 20-gauge
needles used
for mixing

½" 30-gauge
needle used
for injection

color of mixing needles may be different



Check the expiry date on *EGRIFTA SV*® 2 mg vial label.

Inspect the powder to make sure it is not discolored, or has particles in it. It should be white.

- Do not use any of the other vials if the powder is discolored or has particles in it. Contact  **THERA patient support** toll free at 1-833-238-4372 (1-833-23-THERA) right away to report the occurrence.

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 bottles with an alcohol pad and throw the used pad away.

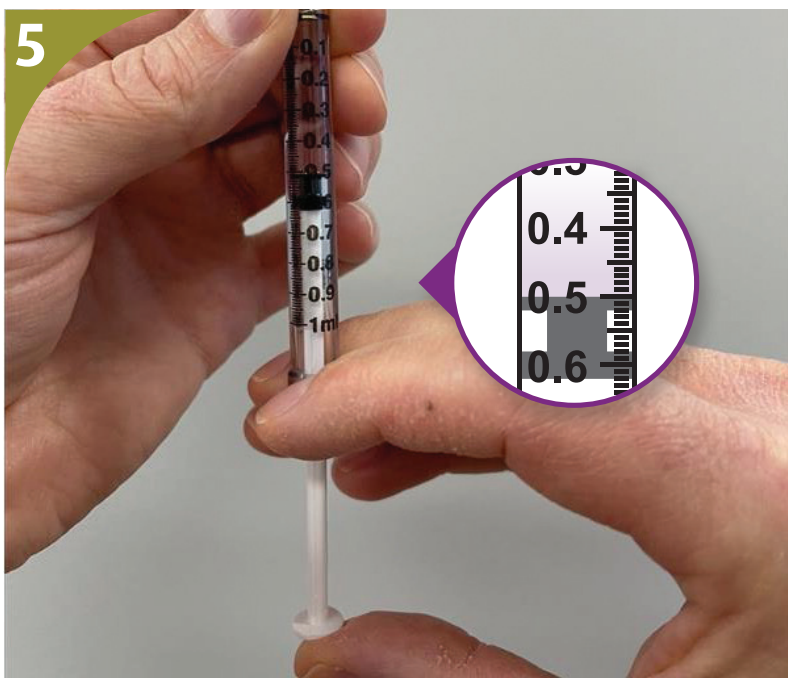
Pull back the plunger slowly to reduce air bubbles inside the syringe, until the Sterile Water reaches the **0.7 mL** mark on the syringe. You may feel some resistance when you pull back the plunger, which is normal.



Remove the syringe tip from the Sterile Water for Injection bottle. With the syringe always upright, tap the syringe with your finger to force any air bubbles to rise to the top.



Slowly push up on the plunger to remove any air bubbles in the syringe to adjust the amount of the Sterile Water in the syringe to 0.5 mL. You should have some Sterile Water coming out of the needle.



Insert the needle into the rubber stopper of the *EGRIFTA SV*[®] 2 mg vial. With the needle at a slight angle, push the plunger down so that the Sterile Water goes down the inside wall of the *EGRIFTA SV*[®] 2 mg vial. (**NOT** directly onto the powder to avoid foaming.)



Remove the needle from the *EGRIFTA SV*[®] 2 mg vial and throw away the syringe and needle.


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.



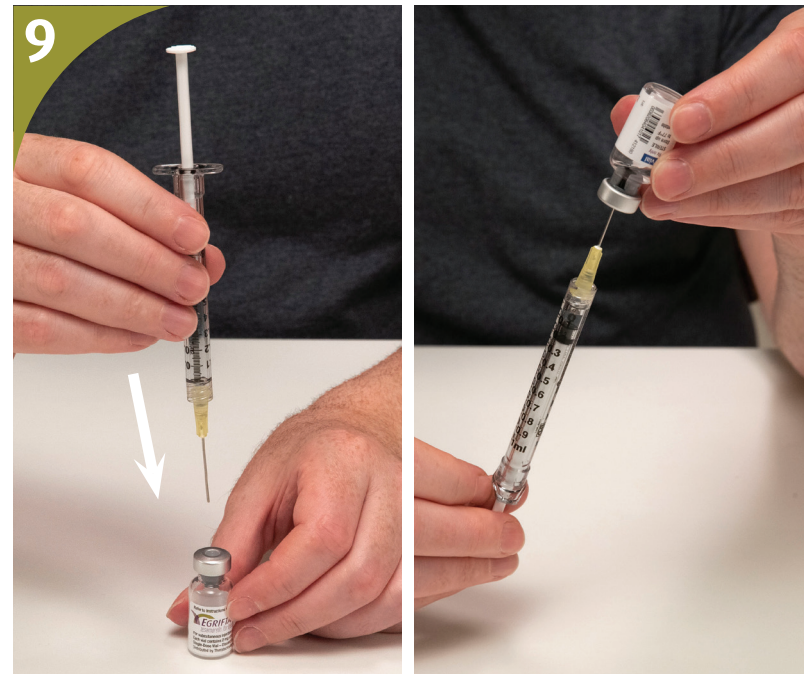
HELPFUL TIP

Once *EGRIFTA SV*[®] has been mixed with Sterile Water, it must be used immediately. It cannot be stored in the mixed form for later use.

- After mixing, the medicine should look clear and colorless, with no particles in it.
- In the event of foaming, leave the *EGRIFTA SV*[®] 2 mg vial aside for a few minutes, until the foam disappears.
- Do not use *EGRIFTA SV*[®] and call your healthcare provider, pharmacist, or contact  **THERA patient support**[®] toll free at 1-833-238-4372 (1-833-23-THERA) right away if the medicine is discolored, or contains particles.

Place the second 1" 20-gauge needle used for mixing onto the second syringe by twisting the needle cap to the right until it closes securely. Pull the protective needle cap straight off. Do not twist the needle cap.

Insert the needle through the rubber stopper of the *EGRIFTA SV*[®] 2 mg vial, and turn the vial and syringe upside down.



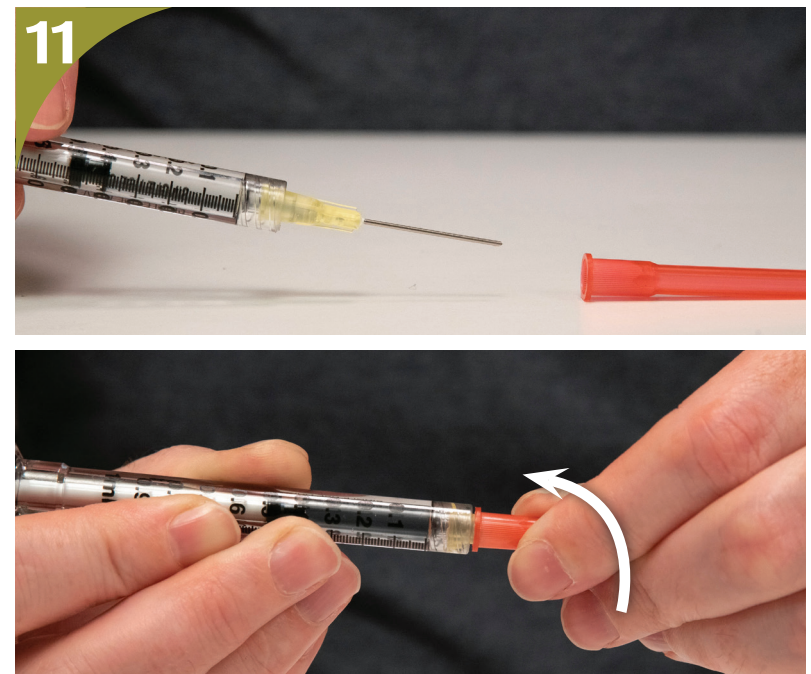
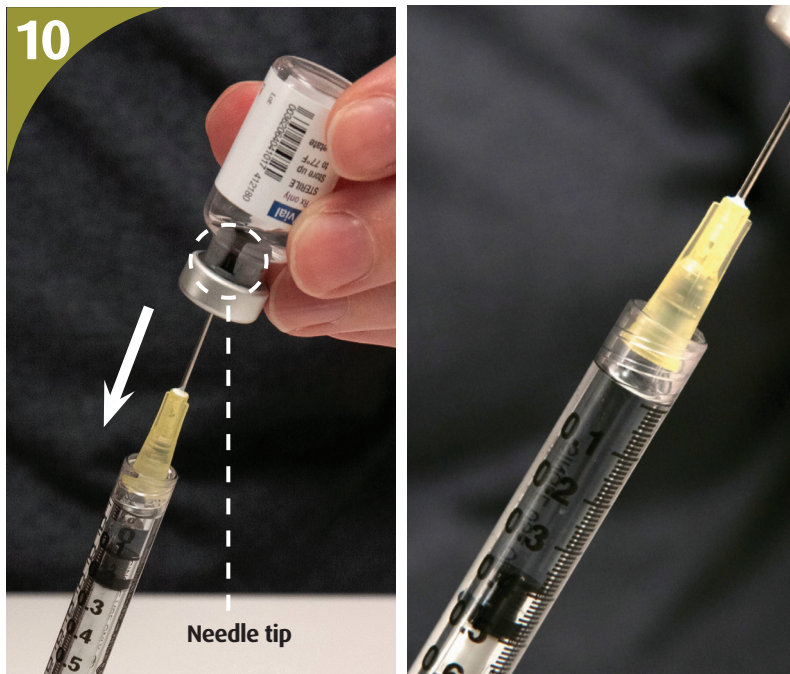
PREPARING TO INJECT *EGRIFTA SV*®

Pull the syringe back through the rubber stopper of the vial, until you see just the tip of the needle, visible in the opening of the rubber stopper.

Pull back on the plunger of the syringe slowly to avoid any air bubbles, 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. Remove the needle from the vial; set the vial aside to be thrown away later.

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.

Push the protective needle cap all the way in or until it snaps shut. **Do not** touch the needle cap until it covers the needle completely.



With the protective needle cap securely in place, remove the needle by twisting the needle cap to the left. Throw away the needle.

Place the ½" 30-gauge needle for injection, with the needle cap and pink shield in place, onto the syringe by twisting the cap to the right until it closes securely.

With the needle facing up, pull the pink shield down away from the white protective cap.

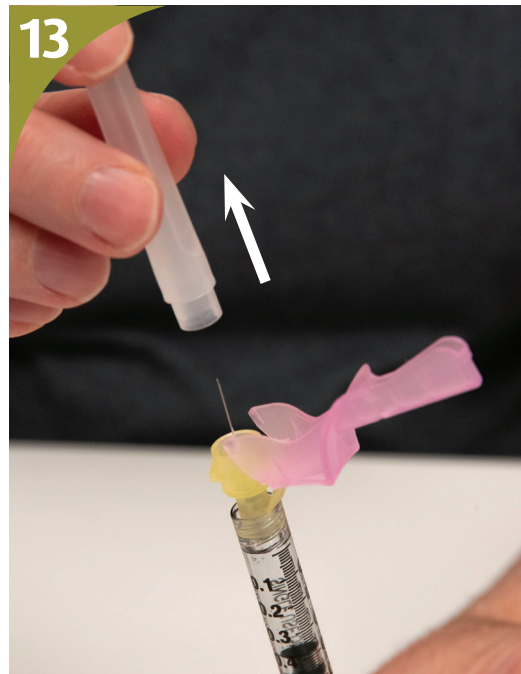
Remove the needle cap by pulling it straight off the needle.

Do not twist the needle cap. **Do not touch the needle.**

Do not move the plunger.

Tap the syringe gently with your finger to force any air bubbles to rise to the top.

Gently push on the plunger to remove any air and bubbles in the syringe, until the medicine in the syringe is at the **0.35 mL** mark of the syringe.



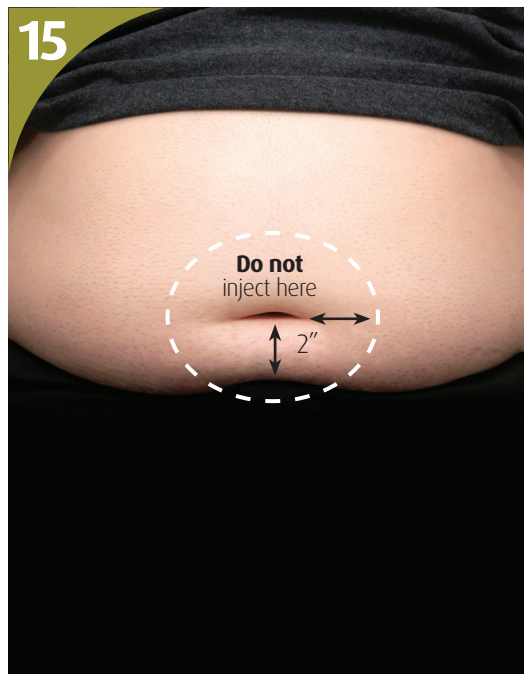
HELPFUL TIP

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

INJECTING EGRIFTA SV®

Inject *EGRIFTA SV*® into the stomach-area (abdomen).

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



Clean the injection-site you have selected with an alcohol pad and let it dry.

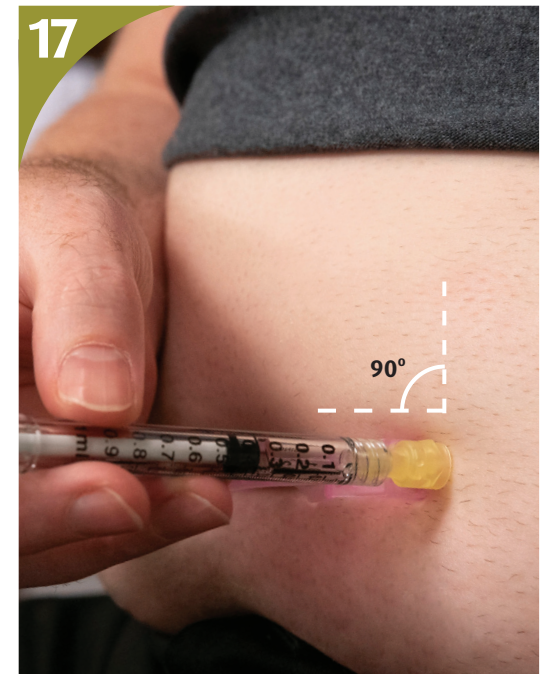
Push the shield away from the needle. Holding the syringe in one hand, with your other hand gently pinch a fold of skin between your thumb and fingers at the cleaned injection-site.



Insert the needle straight into the skin at a 90 degree angle. Most of the needle should go beneath the skin.

Release the pinched area of skin without removing the needle from the skin.

Inject all of the medicine in the syringe, and pull the needle out at the same angle as it was inserted.



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.

HELPFUL TIP

Do not push the plunger until after you release the pinched skin.

FINISHING UP

Press the pink needle shield against a hard, flat surface until you hear a “click” and the injection needle is covered.



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.



DISPOSING OF USED MATERIALS

(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
 - able to 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 disposing of your sharps container, check if there are state or local laws about how you should throw away used needles and syringes. For more information and for specific information about sharps disposal in your state, 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, 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 1-833-238-4372 (1-833-23-THERA) or visit the *EGRIFTA SV*[®]
website at www.EGRIFTASV.com for more information.

Please see page 1 for Important Risk Information and also at www.egriftasv.com



www.egriftasv.com

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



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