

PART III: PATIENT MEDICATION INFORMATION

EGRIFTA[®]
(tesamorelin for injection)

This leaflet is part III of a three-part "Product Monograph" published when EGRIFTA[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about EGRIFTA[®]. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

EGRIFTA[®] is used to reduce the excess in belly fat in patients with HIV and lipodystrophy.

Limitations of use:

- EGRIFTA[®] is not to be used for weight loss management
- EGRIFTA[®] should only be used by patients who could not reduce belly fat using diet and exercise.
- The impact and safety of EGRIFTA[®] on the health of the heart and blood vessels has not been studied.
- It is not known whether taking EGRIFTA[®] helps improve compliance with anti-retroviral medications.

What it does:

EGRIFTA[®] causes the pituitary gland to release growth hormone, which decreases belly fat.

When it should not be used:

Do not use EGRIFTA[®] if you:

- have pituitary gland tumor, pituitary gland surgery or other problems related to your pituitary gland.
- have cancer or are receiving treatment for cancer.
- are allergic to tesamorelin or any of the ingredients in EGRIFTA[®]
- are pregnant or become pregnant. If you become pregnant, stop using EGRIFTA[®] and talk with your healthcare professional.
- are less than 18 years of age.

What the medicinal ingredient is:

tesamorelin acetate

What the nonmedicinal ingredients are:

mannitol, sodium hydroxide and/or hydrochloric acid for pH

adjustment.

What dosage forms it comes in:

Vials: 1 and 2 mg sizes

WARNINGS AND PRECAUTIONS

BEFORE you use EGRIFTA[®] talk to your doctor or pharmacist if:

- Have or have had cancer
- Have diabetes
- Have kidney or liver problems
- Are breastfeeding or plan to breastfeed. It is recommended that HIV infected mothers not breastfeed to avoid risk of passing HIV infection to their baby.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor about all the medicines you take. This includes prescription and over the counter medications, vitamins, and natural health products.

PROPER USE OF THIS MEDICATION

- Take the entire dose (2 mg) of EGRIFTA[®] once a day.
- EGRIFTA[®] is injected under the skin (subcutaneously) of your belly (abdomen).
- After mixing, use EGRIFTA[®] right away.
- Throw away any unused EGRIFTA[®]. Do not store mixed EGRIFTA[®].

Usual dose: 2 mg per day

1 mg vials: two vials per day (taken together in one syringe)

2 mg vials: one vial per day

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss an injection of EGRIFTA[®] you do not have to make up the missed dose. Skip the missed dose and continue with the next scheduled dose. Do not double dose.

Preparing EGRIFTA[®] for administration:

Before you follow these instructions, go over them with your healthcare professional:

- Be sure you understand how to follow the steps for mixing and injecting.
- Practice them with your healthcare professional.
- Ask any questions and talk about concerns you have.
- Make sure to keep your hands and work area clean at all times.

Important information for use of EGRIFTA[®]

- After mixing EGRIFTA[®] with Sterile Water for Injection, it should look clear and colourless, with no particles in it. Do not use EGRIFTA[®] if it looks cloudy, discolored, or if you see particles in it. Talk to your healthcare professional if you have any questions.
- Do not use EGRIFTA[®] after the date on the Medication Box and EGRIFTA[®] vial.
- Do not use a syringe or needle more than 1 time.
- Do not share your EGRIFTA[®] needles with another person. Sharing of needles can result in the transmission of infectious diseases, such as HIV.
- Do not share your EGRIFTA[®] syringe with another person, even if the needle is changed.

If you are missing any supplies from your Medication Box or Injection Box, or if anything looks damaged, call your pharmacist or contact EGRIFTA Support[™] toll-free at 1-844-788-1933 right away.

Important!

There are separate preparation and mixing instructions for the **1 mg vials** and **2 mg vials**. Make sure you follow the correct instructions according to the strength you are using.

1mg Vials:

Preparing for your EGRIFTA[®] injection for **1mg vials**

- Find a well-lit, clean, and flat surface, such as a table.
- Gather your supplies:
 - Medication Box that contains 60 (1 mg) EGRIFTA[®] powder vials.
 - Injection Box that contains the following:

- a) 30 10-mL bottles of Sterile Water for Injection, used for mixing.
- b) 30 sterile 3-mL syringes with needle already attached.
- c) 30 individual 1½" 18-gauge sterile needles, used for mixing
- d) 30 individual ½" 27-gauge sterile injection needles.

- Alcohol pads.
- Sterile gauze.
- A “sharps container” or a puncture-resistant container for throwing away needles after you are done with them. The container should be made from hard plastic or metal. Make sure it has a lid. You can also put used syringes or empty vials of medicine in the container.

How to mix EGRIFTA[®] for **1mg vials** (follow steps 1 to 18)

Step 1: You should have the materials as illustrated and lettered in Figure A below:

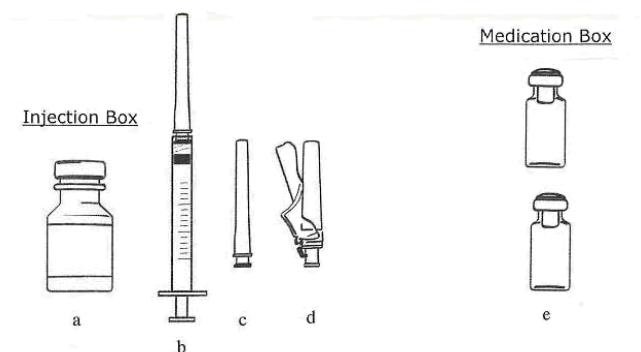


Figure A

- Take out the following from your Injection Box:
 - A Sterile Water for Injection bottle (Figure A, a).
 - A syringe with needle already attached (Figure A, b).
 - A 1½" 18-gauge needle (Figure A, c)
 - A ½" 27-gauge injection needle (Figure A, d).
- Take two EGRIFTA[®] vials (Figure A, e) from the Medication Box. Put the box with the remaining vials back in the refrigerator right away.
- 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 vials of EGRIFTA[®] and Sterile Water.
- Clean the rubber stopper on top of the vials with an alcohol swab.

Step 2: Pick up the syringe with needle (See Figure A, b). Take the needle cap off the syringe and push the needle through the rubber stopper of the Sterile Water bottle (See Figure B). Turn the needle and the bottle upside down, and pull back the plunger of the syringe until the liquid reaches the 2.2 mL mark on the syringe. (See Figure C)

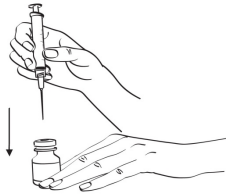


Figure B

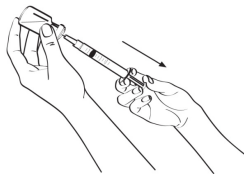


Figure C

Step 3: Take the syringe (with needle attached) out of the Sterile Water bottle.

Step 4: Throw away the rest of the liquid and the bottle of sterile Water for Injection.

Step 5: Insert the needle into one of the EGRIFTA[®] vials. Push the plunger in slowly on a slight angle so water goes down the inside wall of the EGRIFTA[®] vial instead of directly onto the powder. This will avoid foaming. (See Figure D)

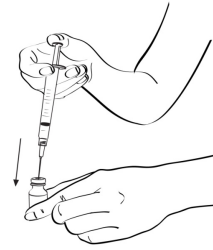


Figure D

Step 6: While keeping the syringe with needle attached in the vial and the vial upright, roll the vial gently in your hands for 30 seconds, until the Sterile Water and EGRIFTA[®] powder are mixed well. Do not shake the vial. The solution should look clear and colorless, with no particles in it. (See Figure E)

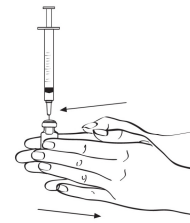


Figure E

Step 7: Keep the syringe with needle attached in the vial and turn both until the syringe is straight up. Pull down on the syringe barrel (not the plunger) until you see just the tip of the needle going through the rubber stopper. Pull back on the plunger until all the liquid inside the vial goes into the syringe. The level of medicine in the syringe should be around the 2.2 mL mark on the syringe. (See Figure F)

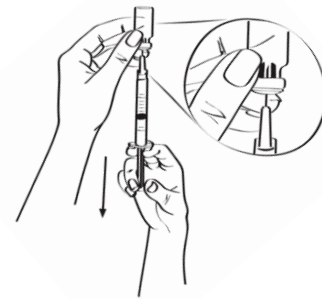


Figure F

Step 8: Take the needle out of the vial. (See Figure G)

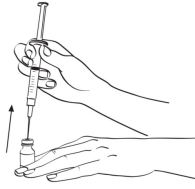


Figure G

Step 9: Place the needle cap on its side against a clean flat surface. Without touching the needle, hold the syringe and slide the needle carefully into the needle cap (See Figure H). Push the cap all the way or until it snaps shut. (See Figure I). Do not touch the cap until it covers the needle completely.



Figure H

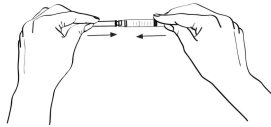


Figure I

Step 10: With the cap on the needle, remove the needle by holding the syringe firmly and twisting the cap counterclockwise (to the left). (See Figure J)

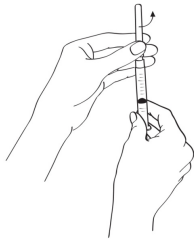


Figure J

Step 11: Place the 1½" 18-gauge mixing needle (Figure A, c), with its needle cap in place, onto the syringe. Hold the syringe firmly and twist the cap clockwise (to the right) until it is tight. (See Figure K)

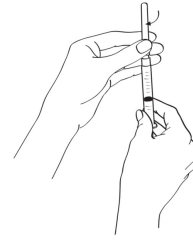


Figure K

Step 12: Remove the needle cap. Insert the needle into the second EGRIFTA® vial (Figure A, e). Push the plunger in slowly on a slight angle so that the mixture goes down the inside wall of the EGRIFTA® vial instead of directly into the powder. This will avoid foaming. (See Figure L)

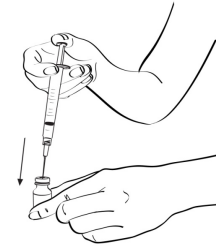


Figure L

Step 13: While keeping the syringe with the needle attached in the vial and the vial upright, roll the vial gently in your hands for 30 seconds, until the solution and powder are mixed well. Do not shake the vial. The solution should look clear and colorless, with no particles in it. (See Figure M)

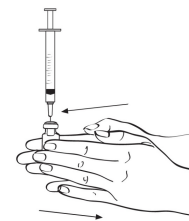


Figure M

Step 14: Keeping the syringe in the vial, turn both until the syringe is facing upright. Carefully pull down on the syringe barrel (not the plunger) until you see just the tip of the needle going through the rubber stopper. Pull back on the plunger until all the liquid inside the vial goes into the syringe. The level of medicine in the syringe should be around the 2.2 mL mark on the syringe. (See Figure N)

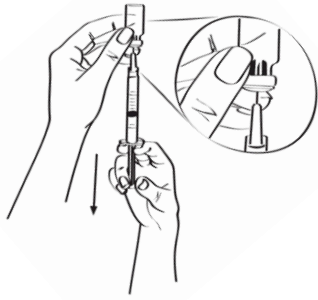


Figure N

Step 15: Take the needle out of the vial. (See Figure O)

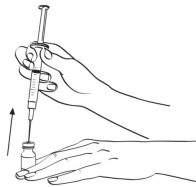


Figure O

Step 16: Place the needle cap on its side against a clean flat surface. Without touching the needle, hold the syringe and slide the needle carefully into the needle cap. (See Figure P) Push the cap all the way until it snaps shut. (See Figure Q) (Do not touch the cap until it covers the needle completely.)

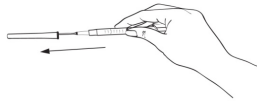


Figure P

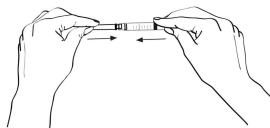


Figure Q

Step 17: With the needle cap on the needle, remove the mixing needle by holding the syringe firmly and twisting the cap counterclockwise (to the left). (See Figure R)

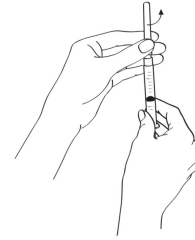


Figure R

Step 18: Place the injection needle (Figure A, d), with its needle cap in place, onto the syringe. Hold the syringe tightly and twist the cap clockwise (to the right) until it is tight. (See Figure S)

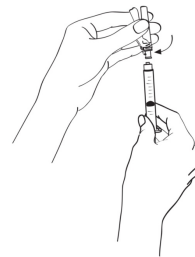


Figure S

You are now ready to Inject EGRIFTA[®]. Go to the section “Where do I inject EGRIFTA[®]” and continue instructions from there.

2 mg Vial

Preparing for your EGRIFTA[®] injection for **2 mg**

- Find a well-lit, clean, and flat surface, such as a table.
- Gather your supplies:
 - Medication Box that contains 30 (2 mg) EGRIFTA[®] powder vials.
 - Injection Box that contains the following:
 - e) 30 10-mL bottles of Sterile Water for Injection, used for mixing.
 - f) 30 sterile 3-mL syringes with needle already attached.
 - g) 30 individual ½" 27-gauge sterile injection needles.
 - Alcohol pads.
 - Sterile gauze.
 - A “sharps container” or a puncture-resistant container for throwing away needles after you are done with them. The container should be made from hard plastic or metal. Make sure it has a lid. You can also put used syringes or empty vials of medicine in the container.

- Take out the following from your Injection Box:
 - A Sterile Water for Injection bottle (Figure A, a).
 - A syringe with needle already attached (Figure A, b).
 - A ½" 27-gauge injection needle (Figure A, c).
- Take one EGRIFTA[®] vial (Figure A, d) from the Medication Box. Put the box with the remaining vials back in the refrigerator right away.
- 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 vials of EGRIFTA[®] and Sterile Water.
 - Clean the rubber stopper on top of the vials with an alcohol swab.

How to mix EGRIFTA[®] for **2mg vials** (follow steps 1 to 11)

Step 1: You should have the materials as illustrated and lettered in Figure A below:

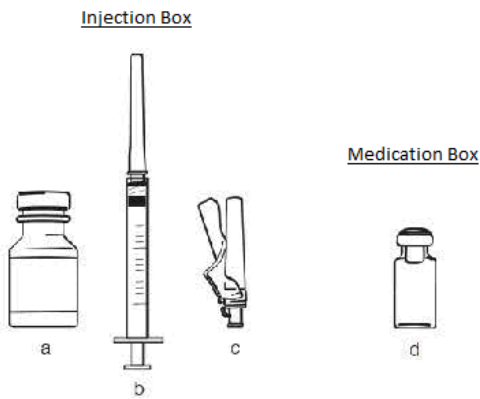


Figure A

- a) Sterile Water for Injection bottle
- b) Syringe with needle already attached
- c) Safety injection needle
- d) EGRIFTA[®] powder medication vial

Step 2: Pick up the syringe with needle (See Figure A, b). Take the needle cap off the syringe and push the needle through the rubber stopper of the bottle of the Sterile Water (See Figure B). Turn the needle and bottle upside down, and pull back the plunger of the syringe until the liquid reaches the 2.1 mL mark on the syringe. (See Figure C)

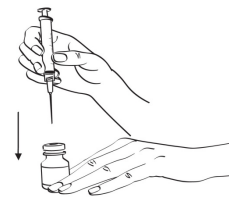


Figure B

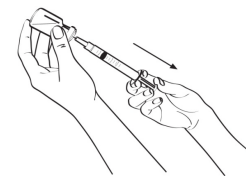


Figure C

Step 3: Take the syringe (with needle attached) out of the Sterile Water bottle.

Step 4: Throw away the rest of the liquid and the bottle of Sterile Water for Injection.

Step 5: Insert the needle into the EGRIFTA[®] vial. Push the plunger in slowly on a slight angle so water goes down the inside wall of the EGRIFTA[®] vial instead of directly onto the powder. This will avoid foaming. (See Figure D)

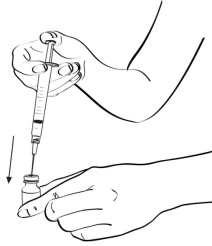


Figure D

Step 6: While keeping the syringe with the needle attached in the vial and the vial upright, roll the vial gently in your hands for 30 seconds, until the Sterile Water and EGRIFTA[®] powder are mixed well. Do not shake the vial. The solution should look clear and colorless, with no particles in it. (See Figure E)

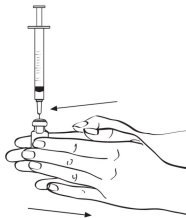


Figure E

Step 7: Keep the syringe in the vial turn both until the syringe is straight up. Carefully pull down on the syringe barrel (not the plunger) until you see just the tip of the needle going through the rubber stopper. Pull back on the plunger until all the liquid inside the vial goes into the syringe. The level of medicine in the syringe should be around the 2.1 mL mark on the syringe. (See Figure F)

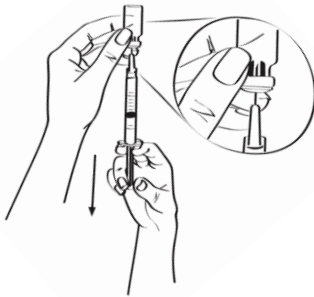


Figure F

Step 8: Take the needle out of the vial. (See Figure G)

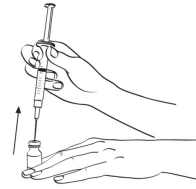


Figure G

Step 9: Place the needle cap on its side against a clean flat surface. Without touching the needle, hold the syringe and slide the needle carefully into the needle cap (See Figure H). Push the cap all the way until it snaps shut. (See Figure I) Do not touch the cap until it covers the needle completely.

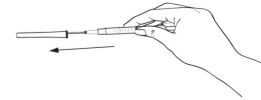


Figure H

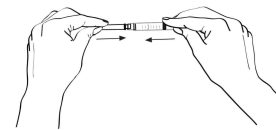


Figure I

Step 10: With the needle cap on the needle, remove the needle by holding the syringe firmly and twisting the cap counterclockwise (to the left). (See Figure J)

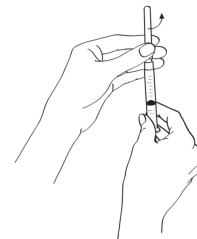


Figure J

Step 11: Place the injection needle (Figure A, c), with its needle cap in place, onto the syringe. Hold the syringe tightly and twist the cap clockwise (to the right) until it is tight. (See Figure K)

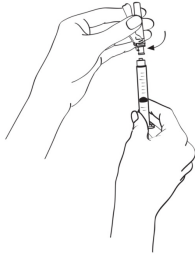


Figure K

You are now ready to inject EGRIFTA[®]. Go to the section “Where do I inject EGRIFTA[®]” and continue instructions from there.

Where do I inject EGRIFTA®?

You should inject EGRIFTA® into the skin on your belly. (See Figure 1)

- Pick an injection site that is around your belly button to the left or right.
- Do not inject into your navel or any area with scar tissue, bruises, reddening, infection, or irritation.
- Avoid areas with any hard bumps from previous injections.
- Change your injection site from one day to the next. This may help prevent bruising or irritation. You may want to keep a note of the date and location of each daily injection to help you remember.



Figure 1

How to inject EGRIFTA® (See Figures 2 – 6)

- Pick up the syringe and pull the cap straight off the injection needle. Do not twist it. (See Figure 2)

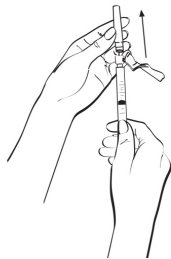


Figure 2

- Tap the syringe gently with your finger to force any air bubbles to rise to the top. Press the plunger to push bubbles out. (See Figure 3)



Figure 3

- Clean the injection site you have selected with an alcohol swab and let it dry. Hold the syringe in one hand. Use your other hand to hold a cleaned fold of skin for your injection. Hold the skin between your thumb and fingers. (See Figure 4)



Figure 4

- Hold the syringe at a right angle to the skin, like a dart. Push the injection needle into the skin with a quick motion. Most of the needle should go beneath the skin surface. (See Figure 5)



Figure 5

- Remove your hand from the pinched area of skin after the needle goes in. Make sure the needle stays in the skin. (See Figure 6)



Figure 6

- Slowly push the plunger all the way down until all of the medicine in the syringe has been injected under the skin.
- Pull the injection needle out of your skin when the syringe is empty:
 - Be careful to pull it out at the same angle you put it in.
 - Flip back the needle shield until it snaps, covering the injection needle completely. Keep pressing until you hear a click, it means the injection needle is protected. (See Figure 7)

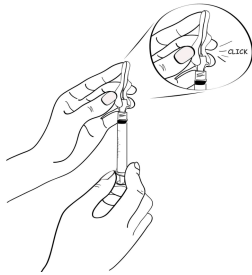


Figure 7

- Use a piece of sterile gauze to rub the injection site clean. If there is bleeding, apply pressure to the injection site with gauze for 30 seconds. If bleeding continues, apply a bandage to the site.

How should I dispose of the used syringes, needles, bottles and vials?

- If you prick someone else with a used needle, that person should contact a healthcare professional right away about the accident.
- Never reuse or recycle needles or syringes.
- Never throw used needles, syringes, or the sharps container into the trash.
- Throw away used syringes, needles, vials and Sterile Water for Injection bottles in a sharps container or hard container like a coffee can.

- Speak to your pharmacist or other healthcare professional about how to throw away used materials. There may be laws about how to throw away used needles and syringes.
- Keep the sharps container away from children and pets.

If you have any questions, call your healthcare professional. You can call EGRIFTA Support™ toll-free at 1-844-788-1933

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, EGRIFTA® can have side effects. Most side effects are mild or moderate in severity. The most common side effects reported with EGRIFTA® are:

- Joint pain
- Pain in legs and arms
- Swelling in your legs
- Muscle pain
- Nausea
- Vomiting
- Rash
- Itching

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Common	Allergic Reaction: rash or hives anywhere on the body or on the skin bigger than the injection area. Swelling of the face, lips, tongue or throat. Difficulty swallowing or breathing.		√

This is not a complete list of side effects. For any unexpected effects while taking EGRIFTA®, contact your doctor or pharmacist.

HOW TO STORE IT

- EGRIFTA[®] has two boxes:
 - Store the Medication Box of EGRIFTA[®] vials in the refrigerator between 2°C and 8°C.
 - Store the Injection Box of Sterile Water for Injection, syringes and needles at room temperature (between 15°C and 30°C).
- Keep EGRIFTA[®] vials away from light.

Keep EGRIFTA[®] and all medications out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- § Report online at www.healthcanada.gc.ca/medeffect
- § Call toll-free at 1-866-234-2345
- § Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: **Canada Vigilance Program**
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect[™] Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

www.Theratechnologies.ca or by contacting **EGRIFTA Support[™] toll-free at 1-844-788-1933**

This leaflet was prepared by Theratechnologies Inc.

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