

**INSTRUCTIONS FOR USE**  
**QFITLIA™** (kew fit lee ah)  
**(fitusiran)**  
**injection, for subcutaneous use**  
**Single-Dose Prefilled Pen (50 mg/0.5 mL)**

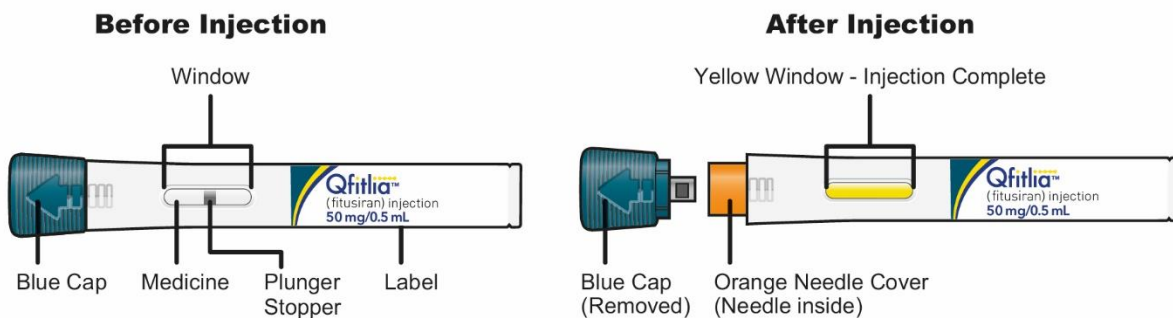
This Instructions for Use contains information on how to inject QFITLIA.

Read this Instructions for Use before using the QFITLIA Prefilled Pen. **Do not inject yourself or someone else until you have been shown how to inject QFITLIA Prefilled Pen.** Your healthcare provider can show you or your caregiver how to prepare and inject a dose of QFITLIA before you try to do it yourself for the first time. Keep this Instructions for Use. Call your healthcare provider if you have any questions.

**QFITLIA Prefilled Pen is only for use in adults and children 12 years of age and older.** It is recommended that QFITLIA Prefilled Pen be given by adults or under adult supervision to children 12 to 17 years of age.

This QFITLIA Prefilled Pen is a single-dose device. It contains 50 mg of QFITLIA for injection under the skin (subcutaneous injection).

The parts of the QFITLIA Prefilled Pen are shown below:



**Important information to know before injecting QFITLIA**

- Read all of the instructions carefully before using the QFITLIA Prefilled Pen.
- Ask your healthcare provider how often you will need to inject the medicine.
- Throw away (dispose of) the used QFITLIA Prefilled Pen right away after use.
- **Do not** re-use a QFITLIA Prefilled Pen.
- QFITLIA Prefilled Pen is for subcutaneous use only. **Do not** inject QFITLIA Prefilled Pen into a vein.





**Storing QFITLIA Prefilled Pen**

- Store QFITLIA Prefilled Pen in the refrigerator between 36°F to 46°F (2°C to 8°C) in the original carton to protect from light.
- QFITLIA Prefilled Pen may be stored at room temperature between 59°F to 86°F (15°C to 30°C) for a single period of up to 3 months within the expiration date printed on the label.
- **Do not** return QFITLIA Prefilled Pen to the refrigerator after storing at room temperature.
- **Do not** shake the QFITLIA Prefilled Pen at any time.
- **Do not** heat the QFITLIA Prefilled Pen.
- **Do not** freeze the QFITLIA Prefilled Pen.
- **Do not** put the QFITLIA Prefilled Pen into direct sunlight.
- **Keep QFITLIA Prefilled Pen and all medicines out of the reach of children.**

**A. Get ready to inject**

**A1) Gather supplies**

Find a clean, flat work surface. Make sure you have the following supplies:

-  • QFITLIA Prefilled Pen
-  • 1 alcohol wipe\*
-  • 1 cotton ball or gauze\*
-  • a sharps disposal container\* (See Step D)

\* Items not included in the carton.

## A2) Check the QFITLIA Prefilled Pen

- **Note:** The plunger stopper in the middle of the Window is normal.



- **Do not** use the QFITLIA Prefilled Pen if it has been dropped or damaged.
- **Do not** use the QFITLIA Prefilled Pen if the Blue Cap is missing or not securely attached.
- **Do not** use the QFITLIA Prefilled Pen if the Window is yellow before use. A yellow Window means the QFITLIA Prefilled Pen has been used.



## A3) Look at the label

### Check the Medicine and Dose



- Check the label to be sure that you have the correct prescribed medicine and dose.

### Check Expiration Date



- **Check the expiration date.**
- **Do not** use the QFITLIA Prefilled Pen if the expiration date has passed.

## A4) Check the medicine



Check Window

- Look at the medicine through the Window, it should be clear and colorless to pale yellow.
- **Note:** You may see air bubbles, this is normal.
- **Do not** use the QFITLIA Prefilled Pen if the liquid is discolored or cloudy, or if it contains visible flakes or particles.

## A5) If QFITLIA Prefilled Pen was stored in the refrigerator, warm up for 30 minutes.



- Lay the QFITLIA Prefilled Pen on a clean, flat surface and let it warm up at room temperature between 59°F to 86°F (15°C to 30°C) for **at least 30** minutes.
- **Do not** heat the QFITLIA Prefilled Pen or put into direct sunlight.

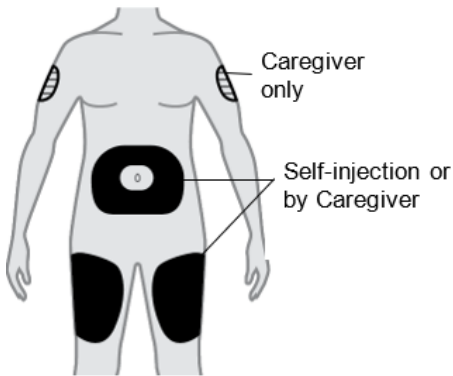
## B. Choose and prepare your injection site

### B1) Wash your hands well with soap and water



### B2) Choose an injection site

- **Thigh**
- **Stomach** except for the 2 inches (5 cm) around your belly button (navel).
- A caregiver can also inject in the outer area of your **upper arm**.
- **Do not** inject into skin that is tender, damaged, has bruises or scars, or into areas with visible veins.
- For subcutaneous use only. **Do not** inject into a vein.
- **Do not** inject through clothes.



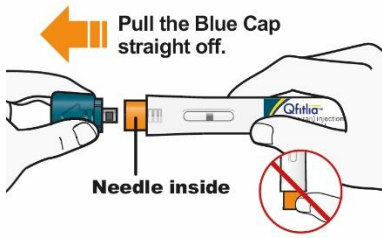
### B3) Prepare the injection site



- Clean the injection site with an alcohol wipe.
- Let the skin dry before injecting.
- **Do not** touch the injection site again or blow on it before the injection.

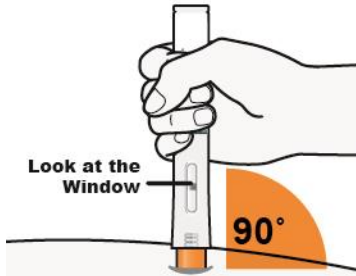
## C. Give the injection

### C1) Remove Blue Cap



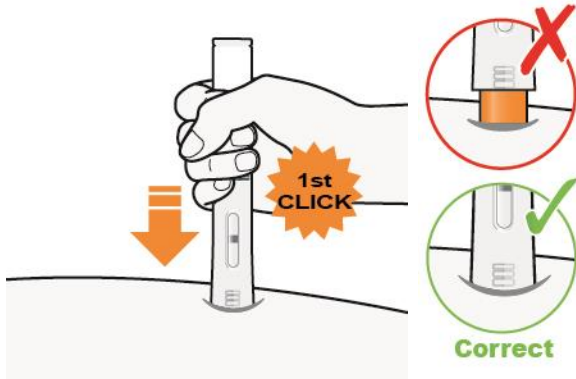
- Remove the Blue Cap by pulling it straight off as shown. **Do not** twist the Blue Cap off.
- **Do not** remove the Blue Cap until you are ready to inject.
- **Do not** touch the Orange Needle Cover with your fingers. The Needle is inside.
- **Do not** put the Blue Cap back on the QFITLIA Prefilled Pen after you have removed it.
- **Note:** You may see a droplet on the needle tip. This is normal.

### C2) Place QFITLIA Prefilled Pen on injection site



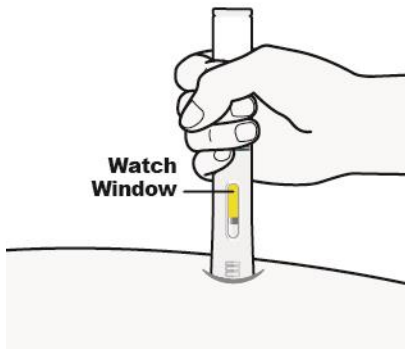
- Hold the QFITLIA Prefilled Pen as shown so you can see the Window.
- Place the Orange Needle Cover on the skin at a 90-degree angle.

### C3) Press down firmly → Watch Window turn fully yellow

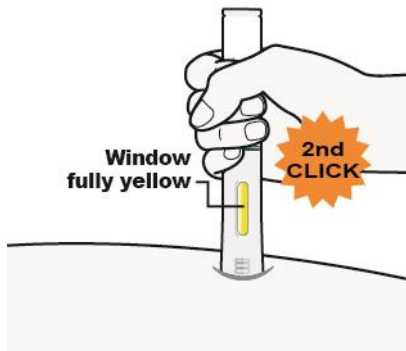


Press down and hold the QFITLIA Prefilled Pen firmly against the skin **until you cannot see the Orange Needle Cover**.

- There will be a “**click**” when the injection starts, **and**
- The Window will start to turn yellow.

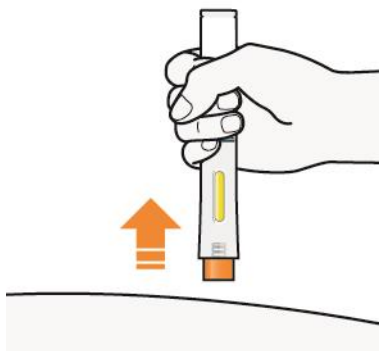


Keep pressing the QFITLIA Prefilled Pen against the skin and watch the Window.



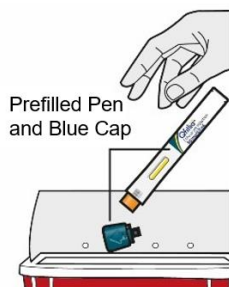
- The Window will turn completely yellow, **and**
- You may hear a **2nd "click."** The injection is complete.

#### C4) Remove



- After you have completed your injection pull straight up to remove QFITLIA Prefilled Pen from the skin. The Orange Needle Cover will cover the needle.
- If you see any blood at the site, lightly dab a cotton ball or gauze pad.
- **Do not** rub the skin after the injection.
- **If the Window does not turn completely yellow**, or if it looks like you may not have received a full dose, call your healthcare provider right away.
- **Do not** give a second dose without speaking to your healthcare provider.

#### D. Throw away (dispose of) used QFITLIA Prefilled Pen



- **Do not** put the Blue Cap back on.

**Keep your sharps disposal container out of the reach of children.**

#### How to dispose of (throw away) QFITLIA Prefilled Pen

- Put your used QFITLIA Prefilled Pen and Blue Cap in an FDA-cleared sharps disposal container right away after use.
- **Do not** dispose of (throw away) QFITLIA Prefilled Pen and Blue Cap 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 QFITLIA Prefilled Pens.
- 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.

Manufactured by:  
Genzyme Corporation  
Cambridge, MA 02141  
A SANOFI COMPANY

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For patent information: <https://www.sanofi.us/en/products-and-resources/patents>

For more information go to [www.QFITLIA.com](http://www.QFITLIA.com) or call 1-800-745-4447.

This Instructions for Use has been approved by the US Food and Drug Administration.  
Issued: March 2025

**INSTRUCTIONS FOR USE**  
**QFITLIA™** (kew fit lee ah)  
**(fitusiran)**  
**injection, for subcutaneous use**  
**Single-Dose Vial (20 mg/0.2 mL)**

This Instructions for Use contains information on how to inject QFITLIA from a vial.

Read this Instructions for Use before using QFITLIA. **Do not inject yourself or someone else until you have been shown how to inject QFITLIA from a vial.** Your healthcare provider can show you or your caregiver how to prepare and inject a dose of QFITLIA from a vial before you do it yourself for the first time. Keep this Instructions for Use. Call your healthcare provider if you have any questions.

**QFITLIA is only for use in adults and children 12 years of age and older.** In children 12 to 17 years of age it is recommended that QFITLIA be given by or under the supervision of an adult.

This QFITLIA vial is for single-use only. It contains 20 mg of QFITLIA for injection under the skin (subcutaneous injection).

**Important information to know before injecting QFITLIA**

- Read all of the instructions carefully before using QFITLIA.
- Ask your healthcare provider how often you will need to inject the medicine.
- Check your prescription label to make sure you draw up the correct medicine dose prescribed by your healthcare provider.
- Throw away (dispose of) the used vial, syringe and needle right away after use.
- Only use the vial one time. After you inject your dose, throw away (dispose of) any unused QFITLIA left in the vial. Do not save any unused QFITLIA in the vial for later use.
- QFITLIA is for subcutaneous use only. **Do not** inject QFITLIA into a vein.

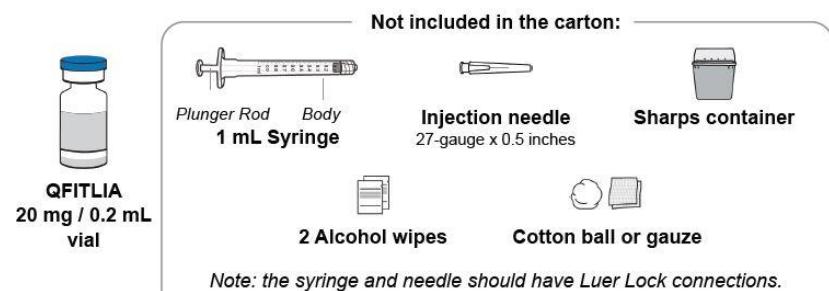
**Storing QFITLIA vial**

- Store QFITLIA vial either in the refrigerator between 36°F to 46°F (2°C to 8°C) or at room temperature between 59°F to 86°F (15°C to 30°C) in the original carton to protect from light.
- **Do not** return QFITLIA vial to the refrigerator after storing at room temperature.
- **Do not** shake the QFITLIA vial at any time.
- **Do not** heat the QFITLIA vial.
- **Do not** freeze the QFITLIA vial.
- **Do not** put the QFITLIA vial into direct sunlight.
- **Keep QFITLIA vial and all medicines out of the reach of children.**

**A. Get ready to inject**

**A1) Gather the supplies.**

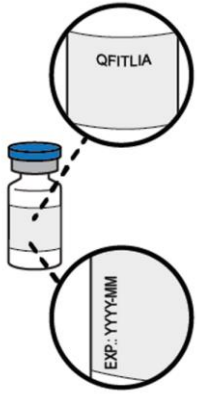
Find a clean, flat work surface. Make sure you have the following supplies:



**A2) Check the vial.**

- **Do not** use the QFITLIA vial if it has been dropped or damaged.
- Check the label on the vial to be sure that you have the correct prescribed medicine and dose.

- **Check expiration date (EXP:).**
- **Do not** use QFITLIA if the expiration date on the vial has passed.



**A3) Check the medicine.**

- Look at the medicine in the vial to make sure it is clear and colorless to pale yellow.
- **Do not** use QFITLIA if the liquid in the vial is discolored or cloudy, or if it contains visible flakes or particles.

**A4) If the QFITLIA vial was stored in the refrigerator, warm up for 30 minutes.**

- Set the QFITLIA vial on a clean, flat surface and let it warm up at room temperature between 59°F to 86°F (15°C to 30°C) for **at least 30** minutes.
- **Do not** heat the QFITLIA vial or put in direct sunlight.

**A5) Wash your hands well with soap and water.**

**A6) Remove the protective cap from the QFITLIA vial.**

**Do not** remove the stopper.



**A7) Wipe the rubber stopper of the vial with an alcohol wipe and allow it to dry.**

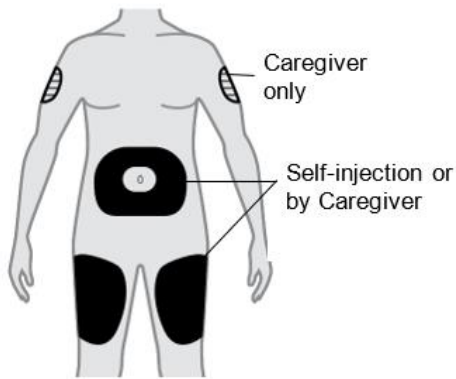


**B. Choose and prepare the injection site**

**B1) Choose the injection site.**

- **Thigh**
- **Stomach** except for the 2 inches (5 cm) around your belly button (navel).
- A caregiver can also inject in the outer area of your **upper arm**.
- **Do not** inject into skin that is tender, damaged, has bruises or scars, or into areas with visible veins.
- **Do not** inject into a vein. For subcutaneous use only.
- **Do not** inject through clothes.





## B2) Prepare the injection site.

- Clean the injection site with an alcohol wipe.
- Let the skin dry before injecting.
- **Do not** touch the injection site again or blow on it before the injection.

## C. Prepare the injection

Contact your healthcare provider if you have any questions about preparing your dose.

### C1) Attach the needle to the syringe and remove the needle cap.

- Attach the needle to the syringe.
- Hold the syringe body and pull the needle cap straight off the syringe.
- **Do not** touch the needle.
- **Do not** recap the needle.

### C2) Withdraw the solution.

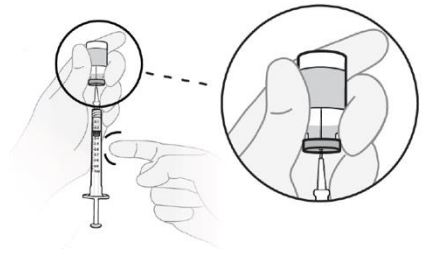
#### Withdraw slightly more than your prescribed dose into the syringe.

- Push the needle through the center of the rubber vial stopper.
- Leave the needle in the vial and turn both the syringe and vial upside down (vial on top).
- Hold the syringe and vial firmly in one hand. Make sure the tip of the needle is in the QFITLIA solution.
- With your other hand, pull back on the plunger rod to withdraw slightly more than your prescribed dose into the syringe.
  - Withdraw slightly more than 0.2 mL for a 20 mg dose.
  - Withdraw slightly more than 0.1 mL for a 10 mg dose.



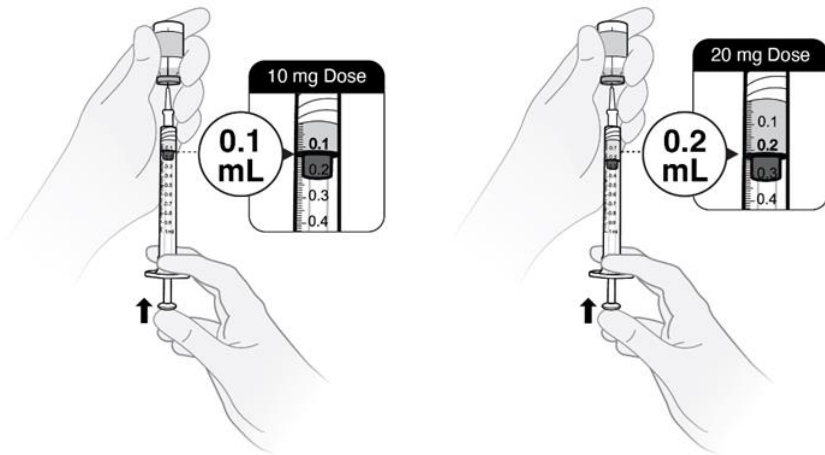
### C3) Check for air bubbles.

- Keep the needle in the vial and make sure both syringe and vial are upside down (vial on top).
- If air bubbles are in the syringe, hold the syringe straight up and tap the side of the syringe until the bubbles float to the top.
- Push the plunger rod up to push the bubbles out of the syringe.



#### C4) Adjust plunger to your prescribed dose.

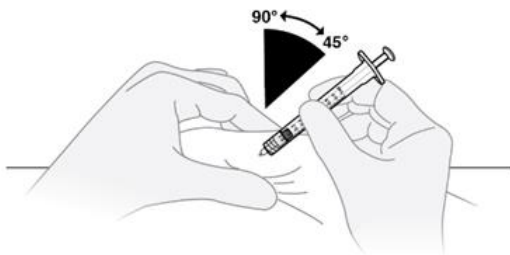
- Push the plunger rod to push solution back into the vial until you have the prescribed dose in the syringe.
  - Push plunger rod to 0.2 mL for a 20 mg dose.
  - Push plunger rod to 0.1 mL for a 10 mg dose.
- If the medicine in the syringe is less than your prescribed dose, repeat steps C2, C3 and C4 until you have your correct dose.
- Remove the needle from the vial. **Do not** let the needle touch anything.



#### D. Inject QFITLIA

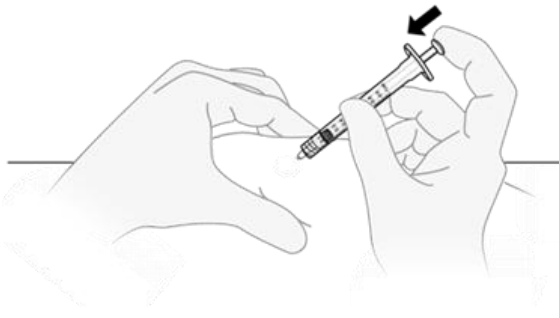
##### D1) Pinch a fold of skin and insert the needle.

Gently pinch a fold of skin at the cleaned injection site. Insert the needle into the skin fold at a 45° to 90° angle.



##### D2) Inject QFITLIA.

Relax the skin pinch. Slowly push the plunger rod all the way to the bottom of the syringe body and inject all of the QFITLIA solution.



**D3) Gently pull out the needle and syringe from the injection site.**

- **Do not** recap the used needle to avoid a needle-stick injury.
- **Do not** rub the skin after the injection.
- If you see any blood at the site, lightly dab it with a cotton ball or gauze pad. If your injection site becomes red or sore, call your healthcare provider right away.

**E. Throw away (dispose of) used vial, needle and syringe**

**E1)** Throw away (dispose of) your used vial, needle and syringe in an FDA-cleared sharps disposal container right away after use.

**Do not** re-use the vial, needle, or syringe.



**Keep your sharps disposal container out of the reach of children.**

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 tightfitting, 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 QFITLIA 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.

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For patent information: <https://www.sanofi.us/en/products-and-resources/patents>

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