MEDICATION GUIDE **Rx Only**

QFITLIA™ (kew fit lee ah)
(fitusiran)
injection, for subcutaneous use

What is the most important information I should know about QFITLIA?

QFITLIA helps your blood form clots. Do not stop using QFITLIA without talking to your healthcare provider. If you miss doses or stop using QFITLIA, you may no longer be protected against bleeding.

Use of a clotting factor concentrate (CFC) or bypassing agent (BPA) to help protect against bleeding must be stopped within 7 days after your first dose of QFITLIA.

Your healthcare provider may prescribe on demand CFC (factor VIII or factor IX products) or BPA if you bleed during treatment with QFITLIA. **Carefully follow your healthcare provider's instructions regarding when to use on-demand treatment with CFC or BPA, including the prescribed dose and timing of the CFC or BPA.**

QFITLIA can cause serious side effects, including:

- **Abnormal blood clotting (thrombotic events).** Serious blood clots have happened in people treated with QFITLIA. QFITLIA can cause blood clots to form in blood vessels in your arms, legs, lungs, heart, brain, eyes, or head. Your risk of blood clots is greater if your antithrombin (AT) blood level is persistently less than 15% or if you have certain other conditions. Get medical help right away if you get any of these signs or symptoms of blood clots during or after treatment with QFITLIA:
  - swelling, pain or redness in arms or legs
  - coughing up blood
  - shortness of breath
  - severe chest pain or tightness of the chest
  - fast heart rate
  - feeling faint or passing out
  - severe or persistent headache
  - difficulty speaking or understanding language
  - feel confused
  - numbness or weakness in your face, arms or legs
  - sudden loss or changes in your vision, eye pain or swelling
- **Gallbladder disease.** QFITLIA can cause gallstones (cholelithiasis) and inflammation of your gallbladder (cholecystitis), which might require surgery to remove your gallbladder. Tell your healthcare provider right away if you develop stomach (abdomen) pain, indigestion, nausea or vomiting. Your healthcare provider may temporarily or permanently stop your treatment with QFITLIA if you develop any of these symptoms.
- **Liver problems.** QFITLIA can cause an increase in your blood liver enzymes. Your healthcare provider will do blood tests to check your liver function before and during treatment with QFITLIA.
- **See "What are the possible side effects of QFITLIA?" for more information about side effects.**

What is QFITLIA?

QFITLIA is a prescription medicine used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children 12 years and older with hemophilia A or B with or without factor VIII or IX inhibitors.

It is not known if QFITLIA is safe and effective in children younger than 12 years of age.

Before receiving QFITLIA, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems
- have a history of gallbladder disease
- are pregnant or plan to become pregnant. It is not known if QFITLIA may harm your unborn baby.
  Females who are able to become pregnant: Hormonal birth control (contraception) may increase your risk of blood clots if used during treatment with QFITLIA. If you use hormonal birth control (contraception), talk to your healthcare provider about effective forms of non-hormonal birth control (contraception) options you can use before starting and during treatment with QFITLIA.
- are breastfeeding or plan to breastfeed. It is not known if QFITLIA passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use QFITLIA?

See the detailed "Instructions for Use" that comes with your QFITLIA for information on how to prepare and inject a dose of QFITLIA, and how to properly throw away (dispose of) the used prefilled pen, vial, needle and syringe.

- Use QFITLIA exactly as prescribed by your healthcare provider.
- Your healthcare provider may change your dose or how often you inject QFITLIA based on your AT blood level to help reduce your chance of abnormal blood clots. Your healthcare provider will check your AT blood level:
  - before starting QFITLIA and at month 1, 3, 5 and 6 during QFITLIA treatment.
  - after any change in your dose of QFITLIA.
  - at yearly routine visits after your healthcare provider determines your target dose.
- It is recommended that QFITLIA be given by or under the supervision of an adult in children 12 to 17 years of age.
- QFITLIA is given as an injection under your skin (subcutaneous) by you or a caregiver.
- Your healthcare provider should show you or your caregiver how to prepare, measure, and inject your dose of QFITLIA before you inject yourself for the first time.
- Do not attempt to inject yourself or another person unless you have been taught how to do so by a healthcare provider.
- After your first dose of QFITLIA, your healthcare provider will let you know when to take your next dose and how much QFITLIA to inject.
- If you miss a dose of QFITLIA on your scheduled day, you should give the dose as soon as possible. After that, resume your dosing schedule either 1 time every month or 1 time every two months from the last dose, as instructed by your healthcare provider.

What are the possible side effects of QFITLIA?

- See **"What is the most important information I should know about QFITLIA?"**

The most common side effects of QFITLIA include:
- viral infection
- common cold symptoms
- bacterial infection

These are not all of the possible side effects of QFITLIA.
Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

How should I store QFITLIA?
- **50 mg 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.
  - Throw away (dispose of) the QFITLIA prefilled pen after 3 months at room temperature or at the expiration date, whichever comes first.
  - Do not return QFITLIA prefilled pen to the refrigerator after storing at room temperature.
- **20 mg Vial**
  - Store QFITLIA vial 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 or prefilled pen at any time.
- Do not heat the QFITLIA vial or prefilled pen.
- Do not freeze the QFITLIA vial or prefilled pen.
- Do not put the QFITLIA vial or prefilled pen into direct sunlight.
- Throw away (dispose of) any unused QFITLIA.

Keep QFITLIA and all medicines out of the reach of children.

General information about the safe and effective use of QFITLIA.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use QFITLIA for a condition for which it was not prescribed. Do not give QFITLIA to other people even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about QFITLIA that is written for health professionals.

What are the ingredients in QFITLIA?
Active ingredient: fitusiran
Inactive ingredients: dibasic sodium phosphate, monobasic sodium phosphate, sodium chloride, and Water for Injection, USP. Phosphoric acid (concentrated) and sodium hydroxide may be added to adjust pH to 7.
Manufactured by: Genzyme Corporation, Cambridge, MA 02141. A SANOFI COMPANY.
For patent information:
https://www.sanofi.us/en/products-and-resources/patents

For more information, go to www.QFITLIA.com or call 1-800-745-4447.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Issued: March 2025

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