

QFITLIA™ (fitusiran)

Patient Guide

This guide for patients and caregivers contains important information you need to be aware of when receiving treatment with QFITLIA™. Please ensure you read the information in this guide, the instructions for use, and package leaflet before starting treatment with QFITLIA™.

This document has been reviewed and approved by
The Saudi Food and Drug Authority (SFDA).

1. Contact information

Patient's name:

Patient's contact (telephone):

Caregiver's name:

Caregiver's contact (telephone):

<Prescribing/treating> physician's name:

<Prescribing/treating> physician's contact (telephone):

Patient's emergency contact name (family/friend):

Patient's emergency contact (family/friend) (telephone):

2. General guidance

This Patient Guide is for personal use and provides you with important information you need to be aware of when receiving treatment with QFITLIA™.

Please complete the contact information above and keep a record of your administered QFITLIA™ dosages (see 'Patient medical record' in Section 7).

Please also complete the accompanying Patient Card. Always keep the Patient Card with you and show it to any healthcare professional involved in your medical care. This includes any doctor, pharmacist, laboratory personnel, nurse, or dentist you see – not just the specialist who prescribes your QFITLIA™.

3. What is QFITLIA™?

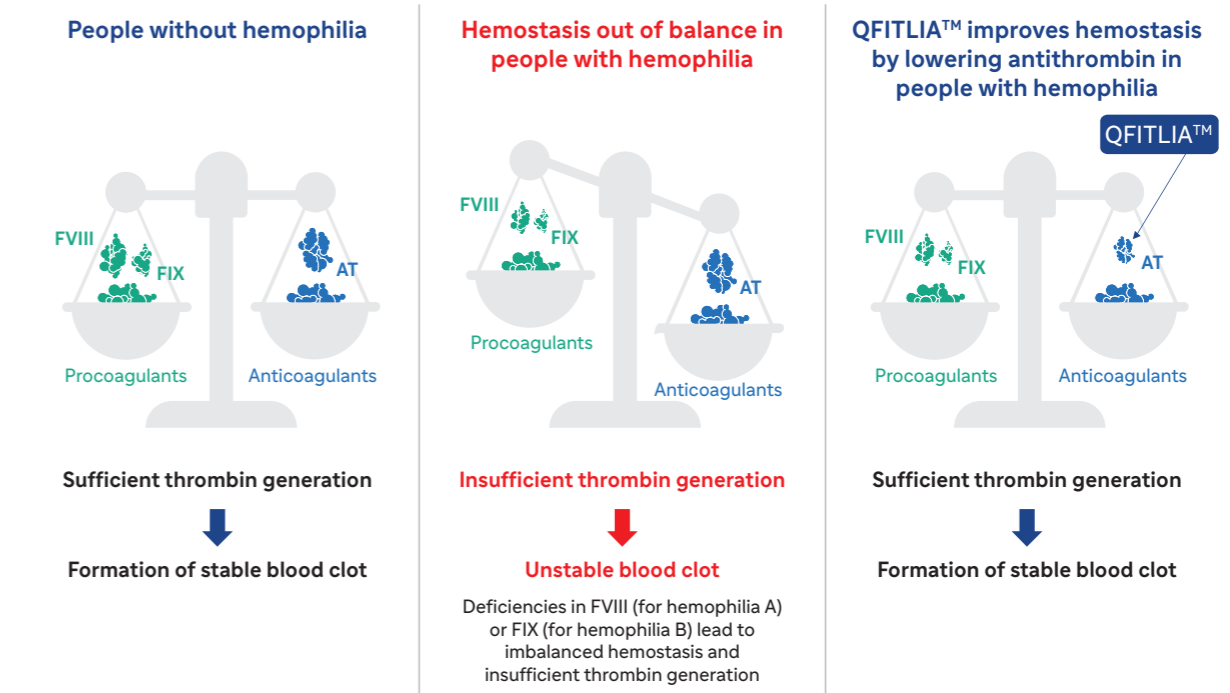
QFITLIA™ is a prescription medicine used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and adolescents, ages 12 years and older, with hemophilia A or B with or without factor VIII or IX inhibitors.

- The safety and effectiveness of QFITLIA™ in pediatric patients younger than 12 years of age have not been established.

In patients with hemophilia A or B, the deficiency in factor VIII or IX leads to insufficient thrombin generation causing the blood to not clot properly (see Figure 1).

QFITLIA™ uses a small interfering ribonucleic acid (siRNA) technology to lower antithrombin, a clotting protein produced in the liver, which leads to increased thrombin generation.


Figure 1. Mode of action of QFITLIA™



AT, antithrombin; FVIII, factor VIII; FIX, factor IX.

4. Treatment with QFITLIA™

- Treatment with QFITLIA™ is recommended to be initiated under the supervision of a qualified healthcare professional experienced in the treatment of hemophilia and/or bleeding disorders.
- You may continue prophylactic use of clotting factor concentrate (CFC) or bypassing agent (BPA) for the first 7 days of QFITLIA™ prophylaxis.
- After the first 7 days of QFITLIA™ treatment, CFC or BPA prophylaxis treatment must be stopped (discontinued).

 Carefully follow your healthcare provider's instructions regarding when to use on-demand CFC or BPA, and which dose and dosing frequency to follow for breakthrough bleed management.

Administration

Use QFITLIA™ exactly as prescribed by your treating physician.

QFITLIA™ is given as an injection under your skin (subcutaneous) with a prefilled pen (50 mg dose; see **Figure 2**) or with a syringe from a vial (20 mg dose; see **Figure 3**) by you or a caregiver.

QFITLIA™ is intended for use under the guidance of a healthcare provider or caregiver.

In adolescents (12 to 17 years of age), it is recommended that QFITLIA™ be administered by or under supervision of an adult.

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 you should take your next dose and which dose to take.

If you miss a dose of QFITLIA™ on your scheduled day, you should administer the dose as soon as possible. After that, resume your dosing schedule either once every month or once every 2 months from the last dose, as instructed by your healthcare provider.

Figure 2. QFITLIA™ prefilled pen (50 mg)



Figure 3. QFITLIA™ vial (20 mg) and syringe



Please refer to the <package leaflet> of QFITLIA™ for additional information and instruction for use.

Monitoring

To minimize the risk of side effects, you will need to undergo blood tests after starting QFITLIA™ treatment to allow your treating physician to:

- **Measure antithrombin activity levels using a specific blood test** to determine the appropriate dose for you after starting QFITLIA™ treatment and at yearly routine visits thereafter. The QFITLIA™ dose should be adjusted if needed, to maintain antithrombin activity between 15–35%. The risk of thrombosis is multifactorial and may be greater in patients with AT activity levels <10% and/or existing comorbidities.
- **Measure liver enzymes** at baseline and then monthly for a period of at least 6 months. Liver transaminase abnormalities have been reported in clinical trials of QFITLIA™.

Breakthrough bleeds

For treatment of breakthrough bleeds, reduced doses and frequency of CFC or BPA must be used.

QFITLIA™ increases the potential for your blood to clot. Carefully follow your healthcare provider's instructions regarding when to use an on-demand CFC or BPA and the recommended dose and schedule to use for breakthrough bleed management.

5. Important risks associated with QFITLIA™ treatment

Like all medicines, QFITLIA™ can cause side effects in some patients, although not everybody gets them.

Blood clots (thrombotic events)

Blood clots (thrombotic events) may occur in blood vessels in your arm, leg, lung, heart, or head.

Get medical help right away if you have any of these signs and symptoms of blood clots during or after treatment with QFITLIA™:

Swelling, pain, or redness in arms or legs
Coughing up blood
Shortness of breath
Chest pain or tightness
Fast heart rate
Feeling faint or passing out
Persistent and severe headache
Difficulty speaking or understanding speech
Numbness or weakness in your face, arms, or legs
Loss of vision, changes in vision, eye pain or swelling

Elevated liver enzymes

QFITLIA™ may cause your liver enzymes to be elevated. Your liver function will be monitored by your healthcare provider prior to initiating QFITLIA™ and at routine intervals for the first 6 months, and periodically thereafter if transaminase levels remain elevated beyond baseline.

6. Important reminders for the patient

- Please complete the Patient Card with your contact information, always keep this card with you, and show it to any healthcare professional involved in your medical care. This includes any doctor, pharmacist, laboratory personnel, nurse, or dentist you see – not just the specialist who prescribes your QFITLIA™.
- Use QFITLIA™ exactly as prescribed by your treating physician and keep a record of dosage and administration date (See ‘Patient medical record’ in **Section 7**).
- Your healthcare provider will measure antithrombin activity levels using a specific blood test to determine the appropriate dose for you after starting QFITLIA™ treatment and at yearly routine visits thereafter.
- In case of breakthrough bleed, reduced dose and frequency of CFC and BPA should be used as per your treating physician’s instructions.
- Contact your treating physician if you experience any of the signs and symptoms described in the Patient Card.
- Report any side effects, overdose, or pregnancy (in women treated with QFITLIA™) to your treating physician.
- Women of childbearing potential should discuss contraception and pregnancy plans with their treating physician. as QFITLIA is not studied on women.

Please report any suspected side effects to your treating physician as well as to the National Pharmacovigilance Center (NPC) at Saudi Food and Drug Authority (SFDA):
 Call Center: 19999
 E-mail: npc.drug@sFDA.gov.sa
 Website: sfda.gov.sa

And to Sanofi Pharmacovigilance:
 Phone: +966-544-284-797
 E-mail: Ksa_pharmacovigilance@sanofi.com

See ‘Important risks associated with QFITLIA™ treatment’ in **Section 5** for more information.

7. Patient medical record

PLEASE KEEP A RECORD OF ALL QFITLIA™ ADMINISTERED DOSAGES.

Patient details		
Patient’s name:.....		
Patient’s date of birth (dd/mm/yyyy):.....		
Patient’s contact (telephone):.....		
Patient’s legal representative contact (telephone):		
QFITLIA™ administration and doses		
	Date of QFITLIA™ administration (dd/mm/yyyy)	Administered QFITLIA™ dose (mg)
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		