

Important side effects

Blood clots (thrombotic events)

Patients may experience blood clots (thrombotic events), which must be treated immediately.



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

Signs of blood clots

- 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
- Severe or persistent 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

Liver transaminase abnormalities may occur during treatment with QFITLIA™.

Your liver function tests will be monitored by your healthcare provider.

Breakthrough bleeds

For treatment of breakthrough bleeds, reduced doses and frequency of clotting factor concentrate or bypassing agent must be used.

Carefully follow your healthcare provider's instructions regarding the use of on-demand clotting factor concentrate or bypassing agent.

Please report any events to your treating physician as well as the National Pharmacovigilance Center (NPC) at Saudi Food and Drug Authority (SFDA):
Call Center: 1999
E-mail: npc.drug@sfd.gov.sa
Website: sfd.gov.sa

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

QFITLIA™ (fitusiran) Patient Card

This Patient Card contains important information you need to be aware of when receiving treatment with QFITLIA™. Please refer to the package leaflet for complete information.

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

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General guidance

Please show this card to any healthcare professional involved in your medical care.

Patient's name:

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Patient's date of birth (dd/mm/yyyy):

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Patient's contact (telephone):

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Patient's legal representative contact
(patients <18 years old) (telephone):

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<Prescribing/treating> physician's name:

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

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

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Date of first QFITLIA™ administration:

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Important information about 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.

QFITLIA™ is given as an injection under the skin (subcutaneous).

QFITLIA™ increases the potential for your blood to clot. Use QFITLIA™ exactly as prescribed by your <prescribing/treating> physician. Carefully follow your healthcare provider's instructions regarding when to use on-demand clotting factor concentrate or bypassing agent and the recommended dose, and which schedule to use for breakthrough bleed management.