

BLEED MANAGEMENT PLAN GUIDANCE FOR QFITLIA[™]



January

March

May

July

September

November

Patient portrayal and hypothetical scenario.

**Qfitlia is a prophylactic treatment only, learn what
is needed to setup a bleed management plan**

This resource and others linked within are not intended to provide medical advice. Speak to your doctor if you have questions.

INDICATION

Qfitlia[™] (fitusiran) 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.

IMPORTANT SAFETY INFORMATION

Qfitlia can cause SERIOUS SIDE EFFECTS, including:

- **Abnormal blood clotting (thrombotic events):** Serious blood clots have occurred in people treated with Qfitlia. Qfitlia can cause blood clots to form in the 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. Your healthcare provider (HCP) will check your AT blood levels before and during treatment with Qfitlia
- **Gallbladder disease:** Qfitlia can cause gallstones and inflammation of your gallbladder, which might require surgery to remove your gallbladder. Tell your HCP right away if you develop stomach pain, indigestion, nausea, or vomiting. Your HCP may temporarily or permanently stop Qfitlia if you develop any of these symptoms

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#), including SERIOUS SIDE EFFECTS, and [Medication Guide](#).

MANAGING BREAKTHROUGH BLEEDS WITH QFITLIA™

You may still get a bleed while on Qfitlia. It is critical to make a bleed management plan with your doctor and follow it should a bleed occur.

Use this checklist **before starting Qfitlia** to make sure you are prepared in case of a breakthrough bleed:

- I discussed my bleed management plan with my doctor
- I know **how much clotting factor concentrate or bypassing agent to take in case of a bleed**
- I know what to do and who to contact in case of a breakthrough bleed

Complete your plan below when speaking with your doctor.

Keep it handy for reference.

My bleed management plan

Name: _____

On-demand medication name and dose: _____

Doctor/hematologist contact information: _____

Notes: _____ Emergency contacts: _____



- If you continue to bleed after using on-demand treatment per your plan, do not repeat the on-demand dose and contact your doctor for guidance
- If you want to switch on-demand medication, it's important to speak to your doctor about your plan as it may change

IMPORTANT SAFETY INFORMATION (CONT'D)

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 HCP. 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.

Please see additional Important Safety Information throughout and accompanying full [Prescribing Information](#), including **SERIOUS SIDE EFFECTS**, and [Medication Guide](#).

FOLLOW YOUR PLAN TO MANAGE BLEEDS

Qfitlia™ is a prophylactic treatment only. It cannot be used to treat a breakthrough bleed. In case of a bleed while using Qfitlia, on-demand treatment is required.

How to get a bleed management plan



Before starting Qfitlia, your doctor will create a bleed management plan with you in case of a breakthrough bleed. Carefully follow your healthcare provider's instructions on when to use on-demand treatment with clotting factor concentrate or bypassing agent, the prescribed dose, and schedule.



Qfitlia works differently from other hemophilia treatments. Using it with on-demand treatment increases the potential for abnormal blood clotting, known as a thrombotic event or thrombosis. As a result, lower and less frequent doses of on-demand treatment should be used to treat breakthrough bleeds.

Risk of thrombosis

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 blood level is persistently less than 15% or if you have certain other conditions.

Thrombotic events were reported in 4 out of 286 (1.4%) trial participants receiving Qfitlia prophylaxis in the extension study for Qfitlia, in which dosing was based on antithrombin levels.

All 4 people had multiple risk factors and/or deviated from the bleed management guidelines, which may have contributed to their increased risk of thrombosis.



It is critical to follow your bleed management plan should a breakthrough bleed occur during treatment with Qfitlia.

IMPORTANT SAFETY INFORMATION (CONT'D)

Your HCP may prescribe on-demand CFC or BPA if you bleed during treatment with Qfitlia. **Carefully follow your HCP's instructions regarding when to use on-demand treatment with CFC or BPA, including the prescribed dose and timing of the CFC or BPA.**

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Pay attention to your usual symptom patterns

This can help you be prepared for a breakthrough bleed. If something feels unusual while taking Qfitlia, don't hesitate to contact your doctor.

Get medical help right away if you get any of these signs or symptoms during or after treatment with Qfitlia, which may or may not be symptoms of a potential blood clot:

- Swelling, pain, or redness in your 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

This list does not include all possible signs/symptoms of a potential blood clot.

Explore resources to support your journey on Qfitlia



Prefer keeping your bleed management plan on an [emergency card](#) or [your phone](#)?



Learn more about the [safety of Qfitlia](#)



Patient portrayal.

Please ask your doctor if you have any questions.

IMPORTANT SAFETY INFORMATION (CONT'D)

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
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What are the possible side effects of Qfitlia?

- **Qfitlia can cause other serious side effects, including an increase in your blood liver enzymes.** Your HCP will do blood tests to check your liver function before and during treatment with Qfitlia
- **The most common side effects of Qfitlia include** viral infection, common cold symptoms, and bacterial infection

These are not all the possible side effects of Qfitlia.

What should I tell my HCP before using Qfitlia?

- **Tell your HCP about all of your medical conditions,** including if you have liver problems, a history of gallbladder disease, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed
- **Females who are able to become pregnant:** Hormonal birth control may increase your risk of blood clots if used during treatment with Qfitlia. Talk to your HCP about effective forms of non-hormonal birth control you can use before starting and during treatment with Qfitlia
- **Tell your HCP about all of the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements

Please see full [Prescribing Information](#), including **SERIOUS SIDE EFFECTS**, and [Medication Guide](#).

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Qfitlia 
(fitusiran) injection
30mg/30mL