

FILSPARI[®] REMS

PATIENT GUIDE



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WHAT IS FILSPARI?

FILSPARI is a prescription medicine used to:

- Slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.
- Reduce proteinuria in adult and pediatric patients aged 8 years and older with focal segmental glomerulosclerosis (FSGS) without nephrotic syndrome.

WHAT IS THE SERIOUS RISK OF FILSPARI?

FILSPARI can cause liver problems. Patients must have their liver function checked before starting FILSPARI then every 3 months during treatment with FILSPARI.

WHAT IS THE FILSPARI RISK EVALUATION AND MITIGATION STRATEGY (REMS)?

Because of the risk of liver problems, the Food and Drug Administration (FDA) has required a program called a Risk Evaluation and Mitigation Strategy (REMS) for FILSPARI. The purpose of the FILSPARI REMS is to make sure the benefits of FILSPARI outweigh the risks. Patients must enroll in the FILSPARI REMS to receive FILSPARI.

HOW DO I ENROLL AND TAKE PART IN THE FILSPARI REMS?

- Read the patient information about FILSPARI and the FILSPARI REMS included in this guide or on the **REMS Website**, www.FILSPARIREMS.com
- Talk with your prescriber to ensure the benefits outweigh the risks of FILSPARI
- Ask questions. Make sure you understand the benefits and risks and what you need to do to enroll and take part in the FILSPARI REMS. Make sure you know how to receive and take FILSPARI
- Before starting FILSPARI:
 - Get a liver test
- During treatment:
 - Get a liver test every 3 months
- You and your prescriber need to choose a certified pharmacy to supply FILSPARI. In some cases, your insurance company may need you to use a specific certified pharmacy
- You and your prescriber must fill out the **Patient Enrollment Form**. After you read and sign it, your prescriber will send it to the FILSPARI REMS
- Your prescription will be mailed to you from a certified pharmacy

WHAT ARE THE FILSPARI REMS REQUIREMENTS FOR ME?

To receive FILSPARI, you must:

- Talk to your prescriber to ensure the benefits outweigh the risks of FILSPARI
- Get a liver test before starting FILSPARI then every 3 months during treatment
- Receive counseling from your prescriber on the risk of liver problems using the **Patient Guide**
- Enroll in the FILSPARI REMS by completing and signing the **Patient Enrollment Form**
- **Be sure you get your liver test every 3 months during treatment. Your certified pharmacy will call you every 3 months to provide counseling and confirm completion of a liver test before shipping your refill. If you do not get your liver test, you may not receive your FILSPARI on time**

HOW WILL I RECEIVE MY FILSPARI?

Only pharmacies that are certified in the FILSPARI REMS can provide FILSPARI to you. In some cases, your insurance company may require you to use a specific certified pharmacy.

Your certified pharmacy ships your FILSPARI refill to you. The certified pharmacy will confirm that you have completed a liver test (every 3 months during treatment) before refilling your prescription.

It is important that your certified pharmacy is able to contact you in order to avoid delays in your refills.

REMINDERS



Get a liver test before starting FILSPARI then every 3 months during treatment



Tell the certified pharmacy when they call whether you completed your liver test



Tell your healthcare provider right away if you have any of these symptoms of liver problems while taking FILSPARI:

- Nausea
- Vomiting
- Pain on the upper right side of your stomach area
- Tiredness
- Loss of appetite
- Yellowing of the skin or the whites of your eyes (jaundice)
- Dark "tea-colored" urine
- Fever
- Itching

If you have questions or concerns about FILSPARI, talk to your healthcare provider. Please visit www.FILSPARIREMS.com or call 1-833-513-1325 Monday through Friday from 8 AM EST to 8 PM EST for more information about the FILSPARI REMS.



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