

# 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.

### WHAT ARE THE SERIOUS RISKS OF FILSPARI?

**FILSPARI can cause liver problems.** Patients must have their liver function checked before starting FILSPARI, monthly for the first 12 months, then every 3 months during treatment with FILSPARI.

**FILSPARI can cause serious birth defects if taken during pregnancy.** Patients must not be pregnant when they start taking FILSPARI or become pregnant during treatment with FILSPARI, or for one month after stopping FILSPARI.

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

Because of the risk of liver problems and serious birth defects, 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](http://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
  - Get a pregnancy test if you are a patient who can become pregnant
- During treatment:
  - Get a liver test every month for the first 12 months, then every 3 months
  - Get a pregnancy test every month if you are a patient who can become pregnant
- One month after stopping FILSPARI:
  - Get a pregnancy test if you are a patient who can become pregnant
- 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, monthly for the first 12 months, 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 monthly for the first 12 months, then every 3 months during treatment. Your certified pharmacy will call you 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**

### **Patients Who Can Become Pregnant:**

You are considered to be a patient who can become pregnant if you have entered puberty, have a uterus, and have not gone through menopause.

To receive FILSPARI, you must:

- Talk to your prescriber to ensure the benefits outweigh the risks of FILSPARI
- Get a pregnancy test before you start taking FILSPARI and before you receive your refills. Your prescriber will order your monthly pregnancy tests during treatment and for one month after discontinuing treatment
- Receive counseling from your prescriber on the risk of serious birth defects using the ***Patient Guide***
- Enroll in the FILSPARI REMS by completing the ***Patient Enrollment Form***
- **Be sure you get your monthly pregnancy test. Your certified pharmacy will call you to provide counseling and confirm completion of a pregnancy test before shipping your refill. If you do not get your monthly pregnancy test, you may not receive your FILSPARI on time**
- Understand that you will be contacted by the FILSPARI REMS if you become pregnant while on FILSPARI or within one month of stopping treatment

Do not have unprotected sex or sexual contact (penis-vaginal) with a partner who can get you pregnant. Use effective birth control during your FILSPARI treatment and for one month after stopping your FILSPARI treatment because the medicine may still be in your body. [Page 6](#) of this guide shows your birth control options.

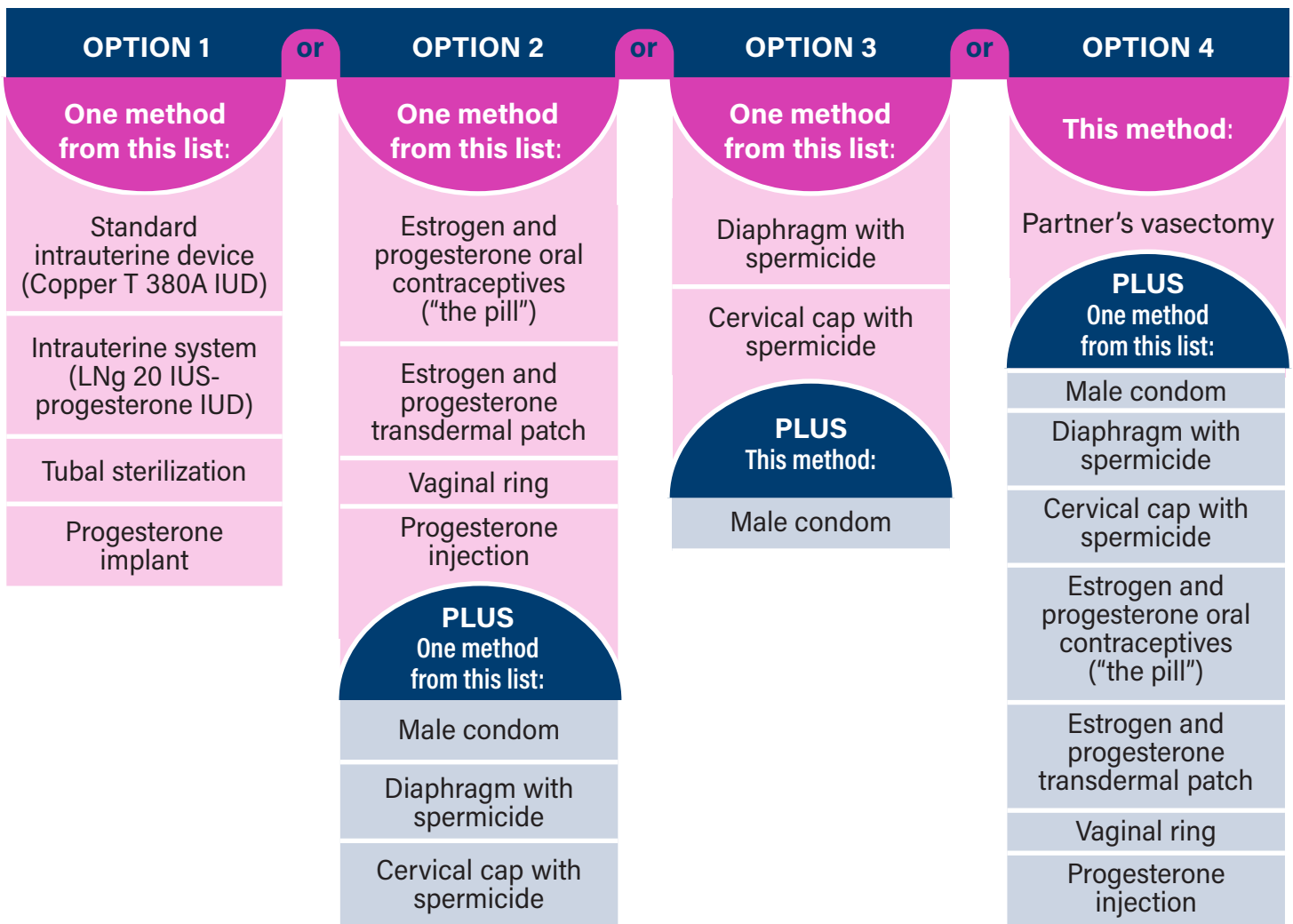
Talk to your prescriber or pharmacist right away if you have unprotected sex, if you think your birth control has failed, or if you think you may be pregnant. Your prescriber may tell you to use emergency birth control. Do not wait until your next appointment to tell your prescriber if there is any delay in having a period or any other reason you think you may be pregnant.

# WHAT ARE MY BIRTH CONTROL OPTIONS IF I CAN BECOME PREGNANT?

If you are a patient who can become pregnant, your prescriber will talk to you about your birth control options before starting FILSPARI. Use the diagram below to help decide what birth control options are best for you. Talk to your prescriber if you have questions about your birth control options. Tell your prescriber if you want to change your birth control method.

You may choose from the four options listed below. More than one birth control method might be needed every time you have sex.

## Effective Birth Control Options



## 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. Before each shipment, the certified pharmacy will confirm that you have completed a liver test (monthly for the first 12 months, then every 3 months during treatment) and completed a pregnancy test (monthly) if you are a patient who can become pregnant 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, monthly for the first 12 months, 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

## REMINDERS FOR PATIENTS WHO CAN BECOME PREGNANT

-  **Do not get pregnant**
-  **Always use effective birth control while taking FILSPARI and for one month after you stop**
-  **Get a pregnancy test before starting FILSPARI, every month during treatment, and one month after discontinuing treatment**
-  **Tell the certified pharmacy when they call whether you have completed your pregnancy test**
-  **Tell your healthcare provider right away if you:**
  - Have unprotected sex
  - Miss a menstrual period
  - Think your birth control has failed
  - Think you may be pregnant

**If you have questions or concerns about FILSPARI, talk to your healthcare provider.**  
Please visit [www.FILSPARIREMS.com](http://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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Phone: 1-833-513-1325

[www.FILSPARIREMS.com](http://www.FILSPARIREMS.com)

Fax: 1-833-483-4736