

FILSPARI® is a once-daily pill designed to lower proteinuria without suppressing the immune system

WHAT IS FILSPARI® (sparsentan)?

FILSPARI is a prescription medicine to lower protein in the urine (proteinuria) in adults with primary IgA nephropathy who are at risk of their disease quickly getting worse. It is not known if FILSPARI is safe and effective in children.

FILSPARI has been approved based on a reduction of proteinuria. Continued approval may require results from an ongoing study to determine whether FILSPARI slows decline in kidney function.

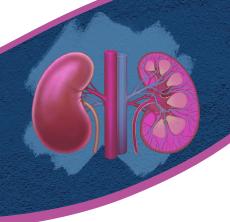
IMPORTANT SAFETY INFORMATION

What is the most important information I should know about FILSPARI?

FILSPARI is only available through the FILSPARI Risk Evaluation and Mitigation Strategy (REMS) Program because of the **serious risk of liver problems and serious birth defects.** Before you begin taking FILSPARI, you must read and agree to all the <u>instructions in the FILSPARI REMS Program</u>.



What is IgA nephropathy?



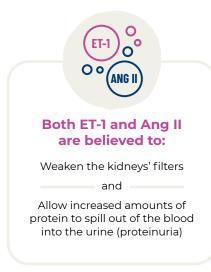
IgA nephropathy is a rare kidney disease

IgA nephropathy should not be ignored. Although a rare kidney disease, it is a leading cause of kidney failure—a loss of kidney function that may require dialysis or a transplant.

This disease occurs when immunoglobulin A (IgA)—an antibody in the blood that helps fight infections—builds up in your kidneys and disrupts their ability to filter waste from your blood.

What happens in the kidneys of people with IgA nephropathy?

With IgA nephropathy, a number of undesirable processes take place in the kidneys. Two molecules, **endothelin-1** (ET-1) and **angiotensin II** (Ang II) are thought to contribute to kidney damage. While not fully understood, scientists believe that ET-1 and Ang II can negatively impact important kidney cells.





ET-1 and Ang II may also create a harmful cycle with proteinuria:

They may increase each other's activity, leading to more proteinuria

and

More proteinuria may lead to more of these molecules



What is proteinuria?

Proteinuria (Pro-teen-vur-ee-ah)

When your kidneys are damaged by IgA nephropathy, they may let increased amounts of protein spill from your blood into your urine. This is called proteinuria.

Some people with IgA nephropathy can have higher levels of proteinuria than others.

Why is it important to monitor your proteinuria?

Routinely monitoring your proteinuria can help you and your doctor make important decisions regarding your disease management. Together with your doctor, be sure to discuss your treatment goals.

Your proteinuria levels are one indicator that can help you and your doctor understand your kidneys' health. In IgA nephropathy, high proteinuria is considered a major risk factor for disease worsening, and important to monitor.

What does your proteinuria mean for your treatment plan?

Elevated levels of protein in your urine may indicate your kidneys' filters have been damaged. If you have consistently elevated proteinuria, your doctor may recommend medication. A medicine that lowers your proteinuria may or may not slow disease progression.

Generally, when it comes to proteinuria, the lower the better. Be sure to discuss your treatment plan with your doctor.

IMPORTANT SAFETY INFORMATION (continued)

FILSPARI can cause changes in liver tests. Some medicines that are like FILSPARI can cause liver failure. Your healthcare provider will do blood tests to check your liver before starting FILSPARI, monthly for the first 12 months, and then every three months during treatment. Your healthcare provider may temporarily stop or permanently stop treatment with FILSPARI if you have changes in your liver tests.

Tell your healthcare provider right away if you develop any of the following signs of liver problems during treatment with FILSPARI: nausea or 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, or itching.



What is FILSPARI®?



Not actual medication bottle.

FILSPARI is a prescription medicine to lower proteinuria in adults with primary IgA nephropathy who are at risk of their disease quickly getting worse

It is a once-daily medicine designed to lower proteinuria without suppressing your immune system.

FILSPARI® is a single pill that works in 2 ways

FILSPARI is specifically designed to simultaneously block both ET-1 and Ang II

(See page 2 for more about ET-1 and Ang II.)



FILSPARI is not a steroid. It is the first and only treatment approved specifically for IgA nephropathy

that does not suppress your immune system

IMPORTANT SAFETY INFORMATION (continued)

FILSPARI can cause serious birth defects if taken during pregnancy. Patients must not be pregnant when they start taking FILSPARI, become pregnant during treatment, or for one month after stopping treatment. Patients who can become pregnant must have a negative pregnancy test before starting FILSPARI, monthly during treatment, and for one month after stopping FILSPARI.

Patients who can become pregnant are those who:

- · have entered puberty, even if they have not started their menstrual period, and
- have a uterus, and
- have not gone through menopause. Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed.



Powerful proteinuria reduction

A clinical study of 281 patients compared FILSPARI® with irbesartan. Irbesartan is a blood pressure medicine called an angiotensin receptor blocker (ARB), a type of medication often used to treat IgA nephropathy.

FILSPARI is a single pill that blocks both ET-1 and Ang II—while irbesartan only blocks Ang II.

At 36 weeks, those taking FILSPARI had 45% less proteinuria than before treatment, compared to 15% for those taking irbesartan





Average grams of protein per gram of creatinine (g/g)	FILSPARI	irbesartan
BEFORE TREATMENT	1.2 g/g	1.2 g/g
AT 36 WEEKS	0.7 g/g	1.0 g/g



Patients who took FILSPARI saw sustained proteinuria reduction through 36 weeks (8.2 months).

On average, at 36 weeks, patients who took FILSPARI saw their proteinuria drop from 1.2 g/g to 0.7 g/g.

Proteinuria below 1 gram per day $(0.88 \ g/g)$ is considered an important treatment goal for patients with IgA nephropathy. Make sure to speak with your doctor about your treatment goals.

IMPORTANT SAFETY INFORMATION (continued)

Patients who cannot become pregnant are those who:

- have not yet entered puberty, or
- do not have a uterus, or
- have gone through menopause. Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed, or
- are infertile for any other medical reason and this infertility is permanent and cannot be reversed.



The FILSPARI REMS Program

A Risk Evaluation and Mitigation Strategy (REMS) is a program designed to help keep you safe. REMS programs are required by the FDA for certain medicines to manage the risk of serious side effects.

FILSPARI® is only available through the FILSPARI REMS Program. The purpose of the program is to reduce risk, monitor for serious side effects, and educate patients about FILSPARI—and to make sure the benefits of FILSPARI outweigh the risks. It's important to understand that your doctor will order certain tests on a routine basis to monitor your health.

Possible serious side effects



Monitoring for liver problems: FILSPARI can cause changes in liver function tests. While no instances of liver damage have occurred in patients taking FILSPARI in the clinical study, some medicines that block ET-1 have caused liver problems. The REMS program helps your doctor monitor your liver function.

Blood tests will be done:

Your doctor may temporarily stop or permanently stop treatment with FILSPARI if you have changes in your liver tests.

Tell your doctor right away if you develop any of the following signs: nausea or vomiting, pain on the upper right side of your stomach area, tiredness, loss of appetite, yellowing of your skin or the white part of your eyes (jaundice), dark "tea-colored" urine, fever, or itching.

IMPORTANT SAFETY INFORMATION (continued)

Patients who can become pregnant must use effective birth control during treatment with FILSPARI and for one month after stopping FILSPARI because the medicine may still be in your body.

 If you have had a tubal sterilization or have an IUD (intrauterine device) or progesterone implant, these methods may be used alone, and no other form of birth control is needed.



The FILSPARI REMS Program (continued)

Possible serious side effects (continued)



Birth defects: Do not take FILSPARI® if you are pregnant, plan to become pregnant, or become pregnant during treatment. Patients who can become pregnant must use effective birth control during treatment with FILSPARI and for 1 month after stopping FILSPARI because the medicine may still be in your body.

Patients who can become pregnant must have a negative pregnancy test:

Review the list of options for acceptable birth control in the **Medication Guide** and discuss with your doctor or gynecologist which options work best for you.

With the FILSPARI REMS Program, you're not alone.

Your nephrologist will help guide you every step of the way.

Visit FILSPARI-REMS.com or call 1-833-513-1325 for more information.

IMPORTANT SAFETY INFORMATION (continued)

- Talk with your healthcare provider or gynecologist (a healthcare provider who specializes in reproduction) to find out about options for effective forms of birth control that you may use to prevent pregnancy during treatment with FILSPARI.
- If you decide that you want to change the form of birth control that you use, talk with your healthcare provider or gynecologist to be sure that you choose another effective form of birth control.
- **Do not have unprotected sex.** Talk to your healthcare provider or pharmacist right away if you have unprotected sex or if you think your birth control has failed. Your healthcare provider may talk with you about using emergency birth control.
- Tell your healthcare provider right away if you miss a menstrual period or think you may be pregnant.

Do not take FILSPARI if you:

- are pregnant, plan to become pregnant, or become pregnant during treatment with FILSPARI. FILSPARI can cause serious birth defects.
- are taking any of these medicines: an angiotensin receptor blocker, an endothelin receptor antagonist, or aliskiren. Ask your healthcare provider if you are not sure if you take one of these medicines.



Potential side effects of FILSPARI®

Tell your doctor if you have any side effect that bothers you or that does not go away.



Other possible serious side effects

FILSPARI® can also cause other serious side effects. Your doctor will help you manage any side effects, and adjust your treatment plan as necessary. Certain possible side effects that your doctor will be monitoring may include:



Low blood pressure: Low blood pressure is common during treatment with FILSPARI and can also be serious. Tell your doctor if you feel dizzy, light-headed, or faint. Stay hydrated while taking FILSPARI.



Worsening of kidney function: Your doctor will check your kidney function during treatment with FILSPARI.



Increased potassium in your blood: This is common during treatment with FILSPARI and can also be serious. Your doctor will check your potassium blood level during treatment with FILSPARI.



Fluid retention: FILSPARI can cause your body to hold too much water. Tell your doctor right away if you have any unusual weight gain or swelling of your ankles or legs.

IMPORTANT SAFETY INFORMATION (continued)

Before taking FILSPARI, tell your healthcare provider about all of your medical conditions, including if you have high blood pressure or heart problems, or liver problems.



Most common side effects

Additional common side effects of FILSPARI® include swelling of the hands, legs, ankles, and feet (peripheral edema), dizziness, and low red blood cells (anemia). These are not all the possible side effects of FILSPARI.

The following table shows the percent of patients who experienced side effects during the FILSPARI clinical study.*

	FILSPARI (202 patients)	irbesartan (202 patients)
Swelling of hands, legs, ankles, and feet	14%	9%
Low blood pressure	14%	6 %
Dizziness	13%	5%
Increased potassium levels	13%	10%
Low red blood cells	5%	2%
Worsening of kidney function	4%	1%
Changes in liver tests (ALT/AST)	2.5%	2%

^{*}These side effects were experienced by at least 2% of those taking FILSPARI. Side effects were recorded over a median time of 1.4 years on treatment.

ALT=alanine aminotransferase; AST=aspartate aminotransferase.

IMPORTANT SAFETY INFORMATION (continued)

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, herbal supplements, grapefruit, and antacid medicines. FILSPARI and other medicines may affect how each other works and cause side effects. Do not start any new medicine until you check with your healthcare provider.

Especially tell your healthcare provider if you take:

- nonsteroidal anti-inflammatory drugs (NSAIDs)
- potassium-containing medicines, potassium supplements or salt substitutes containing potassium
- · blood pressure medicines

What should I avoid while taking FILSPARI?

- Do not get pregnant while taking FILSPARI. If you miss a menstrual period or think you might be pregnant, call your healthcare provider right away.
- It is not known if FILSPARI passes into your breast milk. You should not breastfeed if you are taking FILSPARI. Talk to your healthcare provider about the best way to feed your baby during treatment with FILSPARI.



Starting treatment



Supply and storage

FILSPARI® comes in two dosage strengths

Store FILSPARI at room temperature in its original container. Do not refrigerate.



Not actual size.

Before starting FILSPARI, there are some important considerations to keep in mind:

FILSPARI will be provided to you by a Specialty Pharmacy enrolled in the FILSPARI REMS Program. Your doctor will give you complete details.



Tell your doctor about all your medical conditions, including high blood pressure, heart problems, or liver problems. Discuss all the medications you take, including prescription and over-the-counter medicines, vitamins, herbal supplements, grapefruit, and antacids or acid reducers.

Be sure to tell your doctor if you take:

- nonsteroidal anti-inflammatory drugs (NSAIDs)
- potassium-containing medicines, supplements, or salt substitutes
- · blood pressure medicines



Learn about the potential risks of FILSPARI. Read about possible side effects in the **Medication Guide**, and go over all your questions together with your doctor.



Understand the liver and pregnancy monitoring and contraception requirements as part of the FILSPARI REMS Program.



Recommended treatment schedule

Take FILSPARI® exactly as your doctor tells you to take it.



Take the full daily dose of FILSPARI with water before either your morning or evening meal

Whichever meal you choose to dose prior to, maintain that pattern. It's important to make taking FILSPARI something you do consistently, every day.

It is recommended that you begin FILSPARI as follows:

Initially, you will start FILSPARI at a lower dose (200 mg). Depending on how well you tolerate it, after 2 weeks, your doctor may increase your prescription to the full once-daily dose (400 mg).

Before taking FILSPARI, you should stop taking any angiotensin receptor blockers (ARBs), endothelin receptor antagonists (ERAs), or aliskiren.



Be sure to always follow your doctor's direction when transitioning to FILSPARI. In the clinical study, patients started FILSPARI the day after they stopped taking their ARBs or angiotensin-converting enzyme (ACE) inhibitors (blood pressure medications). No waiting period was required.



All patients must get a liver function test before taking FILSPARI. Patients who can become pregnant must also have a negative pregnancy test.



- For the first 14 days (Weeks 1 & 2), take 200 mg once daily
- After 14 days (Week 3 onward), your doctor may increase your dose to 400 mg once daily, depending on how well you tolerate FILSPARI

If you miss a dose, take the next dose at the regularly scheduled time. Do not take 2 doses at the same time or take extra doses. Reach out to your Travere TotalCare™ team for treatment questions and for help setting up monthly prescription refills.



Support and resources with Total Care





That's why Travere TotalCare™ provides support for FILSPARI® patients to help throughout the treatment journey.

Dedicated to your care, our team offers personal assistance for those taking FILSPARI. From financial support to delivery of medication, we can help with many aspects of managing your IgA nephropathy.

If you experience challenges getting your required FILSPARI REMS Program lab tests, you can have them completed at your home at no cost through the Travere TotalCare™ Lab Support Program.† To learn more, contact us at Travere TotalCare™.



Financial assistance is available

If you have commercial insurance, you may be eligible to pay as little as \$0 per prescription*†

*Copay Assistance Terms and Conditions:

- Program only valid for patients with commercial or private insurance
- · Must be a US resident
- Not valid for patients insured by a federal or state government-funded health plan, including Medicare, Medicare Advantage, Medicaid, and TRICARE
- · Void where the program is prohibited by law
- · Not valid for uninsured patients
- Program does not replace prescription drug coverage or insurance and is not intended to substitute for coverage

†Travere Therapeutics® reserves the right to terminate or modify these programs at any time without notice.



Visit the <u>Travere TotalCare™ website</u> or call 1-833-FILSPARI (1-833-345-7727)

Monday — Friday · 8 AM — 8 PM ET



Frequently asked questions (FAQs)

Why is it important to monitor your proteinuria?

Routinely monitoring your proteinuria can help you and your doctor make important decisions regarding your disease management. Together with your doctor, be sure to discuss your treatment goals.

Do I need to keep taking an ARB or an ACE inhibitor along with FILSPARI?

Tell your doctor about all the medications you take. If you are currently using an angiotensin receptor blocker (ARB) or an angiotensin-converting enzyme (ACE) inhibitor, you should stop taking it before starting FILSPARI®.

Because FILSPARI also blocks angiotensin II (Ang II), taking an ARB or an ACE inhibitor at the same time could increase the risk of certain side effects. ARBs and ACE inhibitors decrease the activity or production of Ang II. The FILSPARI molecule (sparsentan) is specially designed to block Ang II and also to block endothelin-1 (ET-1).

IMPORTANT SAFETY INFORMATION (continued)

What are the possible side effects of FILSPARI?

FILSPARI can cause serious side effects, including:

- Liver problems. See Medication Guide What is the most important information I should know about FILSPARI?
- Serious birth defects. See Medication Guide What is the most important information I should know about FILSPARI?
- Low blood pressure. This is common during treatment with FILSPARI and can also be serious. Tell your healthcare provider if you feel dizzy, light-headed, or faint. Stay hydrated during treatment with FILSPARI.
- Worsening of kidney function. Your healthcare provider will check your kidney function during treatment with FILSPARI.
- Increased potassium in your blood. This is common during treatment with FILSPARI and can also be serious. Your healthcare provider will check your potassium blood level during treatment with FILSPARI.
- Fluid retention. FILSPARI can cause your body to hold too much water. Tell your healthcare provider right away if you have any unusual weight gain or swelling of your ankles or legs.

The most common side effects of FILSPARI include: swelling of the hands, legs, ankles, and feet (peripheral edema), dizziness, and low red blood cells (anemia). These are not all the possible side effects of FILSPARI. Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Travere Therapeutics at 1-877-659-5518.



DISCOVER THE POSSIBILITIES



LOOK FORWARD WITH FILSPARI®

Overally Powerful proteinuria reduction:

In a clinical study at 36 weeks, 141 patients taking FILSPARI had 45% lower proteinuria (average reduction from 1.2 g/g to 0.7 g/g) versus 15% for 140 patients taking irbesartan (average reduction from 1.2 g/g to 1.0 g/g)*

- Works in 2 ways—only approved treatment that blocks both ET-1 and Ang II
- O Does not suppress your immune system

FILSPARI can cause liver problems and serious birth defects. Patients can only receive FILSPARI through a required monitoring program called the FILSPARI REMS Program.

The most common side effects include:

- · Swelling of hands, legs, ankles, and feet
- Low blood pressure
- Dizziness
- Increased potassium in your blood
- Low red blood cells (anemia)

*g/g=grams of protein per gram of creatinine in the urine.







Visit FILSPARI.com

to download a Doctor Discussion Guide and other resources

