

Upgrade to FILSPARI<sup>®</sup>, proven to powerfully lower proteinuria and preserve kidney function by working directly in the kidneys

(sparsentan) tablets 200 mg/400 mg

# FOLLOW ALONG TO LEARN MORE



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## WHAT IS FILSPARI® (sparsentan)?

FILSPARI is a prescription medicine used to slow kidney function decline in adults with a kidney disease called primary IgA nephropathy (IgAN), who are at risk for their disease getting worse. It is not known if FILSPARI is safe and effective in children.

### **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 treatment with FILSPARI, you must read and agree to all the instructions in the FILSPARI REMS Program.

Please see additional Important Safety Information throughout, including serious side effects, and the <u>Medication Guide</u>.

# **3 STEPS TO STARTING FILSPARI®**

# DISCUSS AND SIGN 2 FORMS

First, you will need to sign 2 forms that your doctor submits for you.

#### ( ) The FILSPARI Start form.

- Your signature on the FILSPARI Start form is needed to enroll you in the Travere TotalCare® support program.
- Travere TotalCare<sup>®</sup> is a free program designed to help you get access to FILSPARI as quickly as possible and help you stay on track with your medication
- Soon after you're enrolled, a Travere TotalCare<sup>®</sup> Nurse Educator will reach out to you to provide support

#### The FILSPARI REMS Patient Enrollment form.

After you and your doctor review and you understand the serious safety risks of FILSPARI, you will also need to read and sign the Risk Evaluation and Mitigation Strategy (REMS) Patient Enrollment form.

For more details,

scan to view the

onboarding video

• FILSPARI is only available through this FDA-required program, which helps your doctor monitor serious safety risks so that you can feel confident in your treatment choice

Your doctor will confirm FILSPARI coverage with your insurance company. If you don't have insurance, or if your insurance doesn't cover enough for FILSPARI, additional support may be available.

#### Go to page 5 to learn more.

# COMPLETE YOUR LABS EACH MONTH

The FILSPARI REMS Program requires that your liver function and pregnancy status (for those who can become pregnant) are checked regularly to start and to stay on FILSPARI.

### ( ) Schedule labs with your doctor.

Your liver labs will be needed monthly for the first year, then every 3 months while taking FILSPARI. A pregnancy test (if applicable) will be needed monthly (and if stopping treatment, 1 month after).

Labs can be completed at your doctor's office or at a lab facility. For eligible patients, labs can also be completed at home with assistance from Travere TotalCare®.

Be sure to talk to your doctor about which option is best for you. You can also ask your doctor to order "standing labs" to help complete your labs on time.

#### Go to the right side of page 3 to learn more.

# COORDINATE MONTHLY FILSPARI DELIVERY TO YOUR HOME

FILSPARI will be shipped directly to you.

FILSPARI is only available through certified Specialty Pharmacies. They will verify your labs and then ship FILSPARI directly to you. FILSPARI is not available for pickup at your local pharmacy.

Before the Specialty Pharmacy can ship FILSPARI, they will need to call you to coordinate delivery. Be sure to be on the lookout for this important call every month.

#### **IMPORTANT SAFETY INFORMATION (cont'd)**

#### What is the most important information I should know about FILSPARI? (cont'd)

FILSPARI can cause changes in liver tests. Liver failure was not observed in people treated with FILSPARI in clinical studies, but 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, 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.

# **STARTING TREATMENT**

Once you receive your first shipment of FILSPARI, there are a few considerations to keep in mind.

Before taking FILSPARI, you should stop taking any angiotensin-converting enzyme (ACE) inhibitors, 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 ACE inhibitors (blood pressure medications). No waiting period was required.

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)
- blood pressure medicines

Ask your healthcare provider or pharmacist if you are not sure if you take one of these medicines.

# **Recommended treatment schedule**

#### It is recommended that you begin FILSPARI **FILSPARI** comes in as follows: 2 dosage strengths Ø For the first 14 days (Weeks 1 & 2), take WEEKS 200 mg once daily 1&2

200 mg tablets 400 mg tablets

Not actual size.

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

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



**Take FILSPARI whole** with water before your morning or evening meal.

every day.

### **IMPORTANT SAFETY INFORMATION (cont'd)** What is the most important information I should know about FILSPARI? (cont'd)

Stop taking FILSPARI 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.

Please see additional Important Safety Information throughout, including serious side effects, and the Medication Guide.

· potassium-containing medicines, supplements, or salt substitutes

H2 receptor blocker medicine or proton pump inhibitor (PPI) medicine

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 tolerated

95% of people (192 of 202) in the clinical study reached the 400 mg dose of FILSPARI.

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

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.

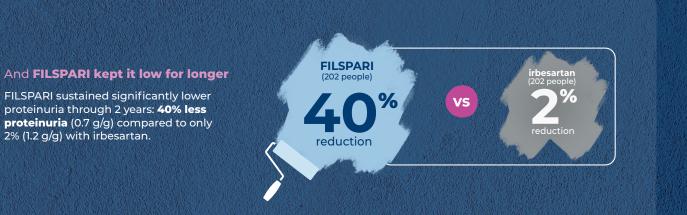


# **UPGRADE YOUR IGAN TREATMENT WITH FILSPARI®**

FILSPARI is the first and only FDA-approved IgA nephropathy (IgAN) treatment that does not suppress your immune system.

# **Powerfully lower proteinuria**

In a clinical study, on average, FILSPARI cut proteinuria in half by 9 months. People started the study with proteinuria levels at 1.2 grams per gram (g/g). At 36 weeks, FILSPARI reduced proteinuria by 45% to 0.7 g/g. Irbesartan, a type of blood pressure medicine often used to treat IgAN, reduced proteinuria by 15% to 1.0 g/g.



# Preserve kidney function for longer

At 2 years, FILSPARI provided 38% better kidney function preservation than irbesartan. The absolute change in eGFR was -6.1 mL/min/1.73 m<sup>2</sup> with FILSPARI (202 people) vs -9.9 mL/min/1.73 m<sup>2</sup> with irbesartan (202 people).

# FILSPARI significantly slowed the loss in kidney function

Through the 2 years of the clinical study, the average decrease in kidney function was only -3.0 mL/min/1.73 m<sup>2</sup> per year with FILSPARI compared to -4.2 mL/min/1.73 m<sup>2</sup> per year with irbesartan.

> Learn more about how FILSPARI powerfully lowers proteinuria and preserves kidney function by working directly in the kidneys. Visit FILSPARI.com

### **IMPORTANT SAFETY INFORMATION (cont'd)**

What is the most important information I should know about FILSPARI? (cont'd)

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.

# POTENTIAL SIDE EFFECTS OF FILSPARI

# **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.

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.

# **Possible serious side effects**



liver failure.

#### Blood tests will be done:

- Ø Before you start treatment with FILSPARI
- O Monthly for the first 12 months
- Severy 3 months after that while taking FILSPARI

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

Stop taking FILSPARI and get medical help 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.



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 before starting treatment with FILSPARI, during treatment with FILSPARI, and for 1 month after stopping FILSPARI because the medicine may still be in their body.

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

- Ø Before starting FILSPARI
- Severy month during treatment

Review the list of options for acceptable birth control in the Medication Guide, "Effective Birth Control Options," and discuss with your doctor or gynecologist which options work best for you.

# **IMPORTANT SAFETY INFORMATION (cont'd)**

### What is the most important information I should know about FILSPARI? (cont'd)

Patients who can become pregnant must use effective birth control before starting treatment with FILSPARI, 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.
- 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.

Please see additional Important Safety Information throughout, including serious side effects, and the Medication Guide.

Monitoring for liver problems: FILSPARI can cause changes in liver tests. Liver failure was not observed in people treated with FILSPARI in the clinical study, but some medicines that are like FILSPARI can cause

• 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



# **POTENTIAL SIDE EFFECTS OF FILSPARI® (cont'd)**

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 (cont'd)**

### What is the most important information I should know about FILSPARI? (cont'd)

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 or pharmacist if you are not sure if you take one of these medicines.

Before taking FILSPARI, tell your healthcare provider about all of your medical conditions, including if you have liver problems, are pregnant or plan to become pregnant during FILSPARI treatment, or are breastfeeding or plan to breastfeed as it is not known if FILSPARI passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during FILSPARI treatment.

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
- H2 receptor blocker medicine or proton pump inhibitor (PPI) medicine

Ask your healthcare provider or pharmacist if you are not sure if you take one of these medicines.

# Most common side effects

The most common side effects seen in the FILSPARI clinical study are shown in the table below.\* These are not all the possible side effects of FILSPARI.

Increased potassium levels

Low blood pressure

Swelling of hands, legs, ankles, and feet

Dizziness

Low red blood cells (anemia)

Worsening kidney function

Changes in liver tests (ALT/AST)

\*These side effects were experienced by at least 2% of those taking FILSPARI. Side effects were recorded over a median time of 110 weeks on treatment.

# **IMPORTANT SAFETY INFORMATION (cont'd)** 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?
- 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.
- provider will check your potassium blood level during treatment with FILSPARI.
- unusual weight gain or swelling of your ankles or legs.

Please see additional Important Safety Information throughout, including serious side effects, and the Medication Guide.

FILSPARI (202 people)	<b>Irbesartan</b> (202 people)
17%	13%
16%	6%
16%	14%
16%	7%
8%	4%
6%	2%
3.5%	4.0%

# • 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

• Increased potassium in your blood. This is common during treatment with FILSPARI and can also be serious. Your healthcare

• Fluid retention. FILSPARI can cause your body to hold too much water. Tell your healthcare provider right away if you have any



# SUPPORT AND RESOURCES WITH **TRAVERE TOTALCARE®**

Living with a rare disease like IgAN can be challenging. That's why Travere TotalCare® provides support for people with IgAN throughout their treatment journey with FILSPARI®. Dedicated to your care, our team offers personal assistance for those taking FILSPARI. From information on financial support to delivery of medication, we can help with many aspects of managing your IgAN.

Each month, your Specialty Pharmacy will call you to follow up on your tests and make sure you get your medication. Talk to your doctor about getting FILSPARI as quickly and smoothly as possible, and about any other concerns you might have about accessing FILSPARI.

# TRAVERE Total Care

# Save key information

In addition to storing key contact information on your phone, it may be helpful to keep important numbers with this Starter Guide. For example, ask your Nurse Educator for your Specialty Pharmacy's phone number, and keep that number here, either written on a printed version or saved as a file on your computer.



# Personalized support to make treatment more affordable

- Eligible, commercially insured patients may pay as little as \$0 per month\*
- If you don't have insurance or if your insurance doesn't cover enough for FILSPARI, additional support may be available
- Patients taking FILSPARI can take advantage of REMS lab testing at home through Travere TotalCare<sup>®</sup>. Eligibility required



### Nurse Educators support your personal treatment journey on FILSPARI

Once you are enrolled in Travere TotalCare®, a Nurse Educator will walk you through the process of starting FILSPARI.

Your Nurse Educator can:

- Help you start and stay on track with your FILSPARI treatment plan
- Connect you with financial support
- Guide you through the process of starting FILSPARI and receiving monthly refills
- Provide updates via text, email, or phone in a variety of languages, including Spanish and Mandarin

#### \*Copay 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 this program at any time without notice.



Scan for support and financial assistance at TravereTotalCare.com

# **HELPFUL HINTS**

- Be sure to answer calls, even from unfamiliar numbers, and return pharmacy calls if you miss them

Please see additional Important Safety Information throughout, including serious side effects, and the Medication Guide.



Ø Be on the lookout for phone calls from Travere TotalCare® and your Specialty Pharmacy



# **3 STEPS TO STARTING FILSPARI®**



# **1** DISCUSS AND SIGN 2 FORMS

You will need to sign 2 forms that your doctor submits for you: the FILSPARI Start form and the FILSPARI REMS Patient Enrollment form.

Find support and financial assistance at **TravereTotalCare.com** or call **1-833-FILSPARI** (1-833-345-7727).

# **2** COMPLETE YOUR LABS EACH MONTH

Monthly labs are needed to start and stay on FILSPARI. Your liver labs will be needed monthly for the first year, then every 3 months while taking FILSPARI. A pregnancy test (if applicable) will be needed monthly (and if stopping treatment, 1 month after).

For any questions, visit FILSPARI-REMS.com or call 1-833-513-1325.

# **3** COORDINATE MONTHLY FILSPARI DELIVERY TO YOUR HOME

Your Specialty Pharmacy will contact you by phone to confirm your monthly treatment shipment. Be sure to answer their call.

# **IMPORTANT SAFETY INFORMATION (cont'd)**

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. You may also report side effects to Travere Therapeutics at 1-877-659-5518.

Please see additional Important Safety Information throughout, including serious side effects, and the <u>Medication Guide</u>.





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