

Thank you for considering FILSPARI™ (sparsentan) for your patients. This checklist will help you implement the REMS certification needed to prescribe FILSPARI and initiate treatment, while ensuring your patient's health and safety remain paramount.

STEP 1

Become eligible to prescribe FILSPARI to your patients

Complete FILSPARI REMS certification

A one-time Risk Evaluation and Mitigation Strategies (REMS) certification is required and must be implemented prior to prescribing FILSPARI for your patients. You can find the REMS guide and enrollment form in your Traverre Starter Kit for FILSPARI Treatment or online at www.FILSPARI-REMS.com.

- Review the FILSPARI REMS Prescriber and Pharmacy Guide
- Complete and submit the Prescriber REMS One-Time Enrollment Form

For more information or to download additional copies of the REMS forms and resources, visit FILSPARI-REMS.com.



STEP 2

Prepare your patients for treatment with FILSPARI

Before initiating treatment, assess liver function and pregnancy status of your patient

- Aminotransferase levels and total bilirubin must be established before starting treatment
Do not prescribe FILSPARI for patients with elevated aminotransferases (>3x ULN).
 - After initiation, levels should be assessed monthly during the first year of treatment, then every 3 months thereafter
- Confirm a negative pregnancy test prior to and monthly during treatment, as well as one month following discontinuation of FILSPARI treatment

Visit FILSPARIhcp.com for Important Safety Information and full Prescribing Information.



STEP 3

Getting your patients started on FILSPARI

Partner with your patients to get them started on FILSPARI

- Open the FILSPARI Patient Start Packet located in your Traverre Starter Kit for FILSPARI Treatment and review the REMS Patient Guide with your patient
- Complete the REMS Patient Enrollment Form as found in your FILSPARI Patient Start Packet
- Complete the Traverre TotalCare™ Patient Start Form included in your FILSPARI Patient Start Packet

Contact your Traverre Representative for additional Patient Start Packets or visit TraverreTotalCare.com to download more Patient Start Forms, REMS Patient Enrollment Forms, and other resources.



STEP 4

Helping your patients access FILSPARI

Your Traverre TotalCare™ team is dedicated to providing you and your patients with comprehensive support

- Review the Access Resources provided in your Traverre Starter Kit for FILSPARI Treatment:
 - Prior Authorization Checklist
 - Appeals Checklist
 - Sample Statement of Medical Necessity Letter
 - Sample Appeal Letter

Traverre TotalCare™ 1-833-345-7727 Monday — Friday • 8 AM — 8 PM EST
For more information, visit TraverreTotalCare.com



INDICATIONS & USAGE

FILSPARI™ (sparsentan) is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g. This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether FILSPARI slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: HEPATOTOXICITY AND EMBRYO-FETAL TOXICITY

Because of the risks of hepatotoxicity and birth defects, FILSPARI is available only through a restricted program called the FILSPARI REMS. Under the FILSPARI REMS, prescribers, patients and pharmacies must enroll in the program.

Hepatotoxicity

Some Endothelin Receptor Antagonists (ERAs) have caused elevations of aminotransferases, hepatotoxicity, and liver failure. In clinical studies, elevations in aminotransferases (ALT or AST) of at least 3-times the Upper Limit of Normal (ULN) have been observed in up to 2.5% of FILSPARI-treated patients, including cases confirmed with rechallenge.

Measure transaminases and bilirubin before initiating treatment and monthly for the first 12 months, and then every 3 months during treatment. Interrupt treatment and closely monitor patients who develop aminotransferase elevations more than 3x ULN.

FILSPARI should generally be avoided in patients with elevated aminotransferases (>3x ULN) at baseline because monitoring for hepatotoxicity may be more difficult and these patients may be at increased risk for serious hepatotoxicity.

Embryo-Fetal Toxicity

FILSPARI can cause major birth defects if used by pregnant patients based on animal data. Therefore, pregnancy testing is required before the initiation of treatment, during treatment and one month after discontinuation of treatment with FILSPARI. Patients who can become pregnant must use effective contraception before the initiation of treatment, during treatment, and for one month after discontinuation of treatment with FILSPARI.

Contraindications: FILSPARI is contraindicated in patients who are pregnant. Do not coadminister FILSPARI with angiotensin receptor blockers (ARBs), ERAs, or aliskiren.

Warnings and Precautions

- **Hepatotoxicity:** Elevations in ALT or AST of at least 3-fold ULN have been observed. To reduce the risk of potential serious hepatotoxicity, measure serum aminotransferase levels and total bilirubin prior to initiation of treatment, monthly for the first 12 months, then every 3 months during treatment.

Advise patients with symptoms suggesting hepatotoxicity (nausea, vomiting, right upper quadrant pain, fatigue, anorexia, jaundice, dark urine, fever, or itching) to immediately stop treatment with FILSPARI and seek medical attention. If aminotransferase levels are abnormal at any time during treatment, interrupt FILSPARI and monitor as recommended.

Consider re-initiation of FILSPARI only when hepatic enzyme levels and bilirubin return to pretreatment values and only in patients who have not experienced clinical symptoms of hepatotoxicity. Avoid initiation of FILSPARI in patients with elevated aminotransferases (>3x ULN) prior to drug initiation.

- **Embryo-Fetal Toxicity:** FILSPARI can cause fetal harm. Advise patients who can become pregnant of the potential risk to a fetus. Obtain a pregnancy test and advise patients who can become pregnant to use effective contraception prior to, during, and one month after discontinuation of FILSPARI treatment.
- **FILSPARI REMS:** FILSPARI is available only through a restricted program under a REMS called the FILSPARI REMS. Important requirements include:
 - Prescribers must be certified with the FILSPARI REMS by enrolling and completing training.
 - All patients must enroll in the FILSPARI REMS prior to initiating treatment and comply with monitoring requirements.
 - Pharmacies that dispense FILSPARI must be certified with the FILSPARI REMS and must dispense only to patients who are authorized to receive FILSPARI.

Further information is available at www.filsparirems.com or 1-833-513-1325.

- **Hypotension:** There was a greater incidence of hypotension-associated adverse events, some serious, including dizziness, in patients treated with FILSPARI compared to irbesartan. In patients at risk for hypotension, consider eliminating or adjusting other antihypertensive medications and maintaining appropriate volume status. If hypotension develops, consider a dose reduction or dose interruption of FILSPARI.
- **Acute Kidney Injury:** Monitor kidney function periodically. Patients whose kidney function may depend in part on the activity of the renin-angiotensin system (e.g., patients with renal artery stenosis, chronic kidney disease, severe congestive heart failure, or volume depletion) may be at particular risk of developing acute kidney injury on FILSPARI. Consider withholding or discontinuing therapy in patients who develop a clinically significant decrease in kidney function while on FILSPARI.
- **Hyperkalemia:** Monitor serum potassium periodically and treat appropriately. Patients with advanced kidney disease, taking concomitant potassium-increasing drugs (e.g., potassium supplements, potassium-sparing diuretics), or using potassium-containing salt substitutes are at increased risk for developing hyperkalemia. Dosage reduction or discontinuation of FILSPARI may be required.
- **Fluid Retention:** Fluid retention may occur with ERAs, and has been observed with FILSPARI. If clinically significant fluid retention develops, after evaluation, consider modifying the dose of FILSPARI.

Most common adverse reactions ($\geq 5\%$) are peripheral edema, hypotension (including orthostatic hypotension), dizziness, hyperkalemia, and anemia.

Drug interactions

- **Renin-Angiotensin System (RAS) Inhibitors and ERAs:** Do not coadminister FILSPARI with ARBs, ERAs, or aliskiren.
- **Strong and Moderate CYP3A Inhibitors:** Avoid concomitant use of FILSPARI with strong CYP3A inhibitors. Monitor blood pressure, serum potassium, edema, and kidney function regularly when used concomitantly with moderate CYP3A inhibitors.
- **Strong CYP3A Inducers:** Avoid concomitant use with a strong CYP3A inducer.
- **Antacids and Acid Reducing Agents:** Administer FILSPARI 2 hours before or after administration of antacids. Avoid concomitant use of acid reducing agents (histamine H2 receptor antagonist and PPI proton pump inhibitor) with FILSPARI.
- **Non-Steroidal Anti-Inflammatory Agents (NSAIDs), Including Selective Cyclooxygenase-2 (COX-2) Inhibitors:** Monitor for signs of worsening renal function.
- **CYP2B6, 2C9, and 2C19 Substrates:** Monitor for efficacy of the concurrently administered CYP2B6, 2C9, and 2C19 substrates and consider dosage adjustment in accordance with the Prescribing Information.
- **P-gp and BCRP Substrates:** Avoid concomitant use of sensitive substrates of P-gp and BCRP with FILSPARI.
- **Agents Increasing Serum Potassium:** Monitor serum potassium frequently. Concomitant use of FILSPARI with potassium-sparing diuretics, potassium supplements, potassium-containing salt substitutes, or other drugs that raise serum potassium levels may result in hyperkalemia.

Use in specific populations

- **Pregnancy / Females and Males of Reproductive Potential:** FILSPARI can cause fetal harm, including birth defects and fetal death, when administered to a pregnant patient and is contraindicated during pregnancy.
 - **Pregnancy Testing / Contraception:** Verify the pregnancy status and effective method of contraception prior to, during, and one month after discontinuation of FILSPARI treatment. The patient should contact their physician immediately for pregnancy testing if onset of menses is delayed or pregnancy is suspected.
- **Lactation:** Advise patients not to breastfeed during treatment with FILSPARI.

Hepatic Impairment: Avoid use of FILSPARI in patients with any hepatic impairment (Child-Pugh class A-C).

Please see the accompanying full Prescribing Information, including BOXED WARNING, for additional Important Safety Information.

Reference: FILSPARI Prescribing Information, San Diego, CA; Travers Therapeutics, Inc.

© 2023 Travers Therapeutics, Inc. FILSPARI and Travers TotalCare are trademarks of Travers Therapeutics, Inc. All rights reserved. 02/2023 SPA0288

