FILSPARI® (sparsentan) tablets 200 mg | 100 mg

For adults with IgA nephropathy

Included in **KDIGO 2025 Guideline**[1]

A STRONGER FOUNDATION FOR KIDNEY PRESERVATION[2]

Consistent ne_ nroprotection.*
Proven superiority over 2 years.†,2,3†

*FILSPARI simultaneously targets ET-1 and Ang II pathways.[2]
†In the 2-year PROTECT trial (N=404) that evaluated the effect on proteinuria and kidney function vs irbesartan.[2]

‡Source: Komodo Claims, total Rx data through 01/2026.4

ISI
PI
REFS

Replace your patients' RAS inhibitor with dual-acting FILSPARI®[2]

Ang II=angiotensin II; ET-1=endothelin-1; IgA=immunoglobulin A; IgAN=immunoglobulin A nephropathy; KDIGO=Kidney Disease: Improving Global Outcomes; RAS=renin-angiotensin system.

INDICATIONS & USAGE
FILSPARI® (sparsentan) is indicated to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.

IMPORTANT SAFETY INFORMATION
BOXED WARNING: HEPATOTOXICITY AND EMBRYO-FETAL TOXICITY
Because of the risk of hepatotoxicity, 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 3.5% of FILSPARI-treated patients, including cases confirmed with rechallenge.

Measure transaminases and bilirubin before initiating treatment 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 is contraindicated for use during pregnancy because it may cause fetal harm if used by pregnant patients. Therefore, in patients who can become pregnant, exclude pregnancy prior to initiation of FILSPARI. Advise use of effective contraception before the initiation of treatment, during treatment, and for two weeks after discontinuation of treatment with FILSPARI. When pregnancy is detected, discontinue FILSPARI as soon as possible.

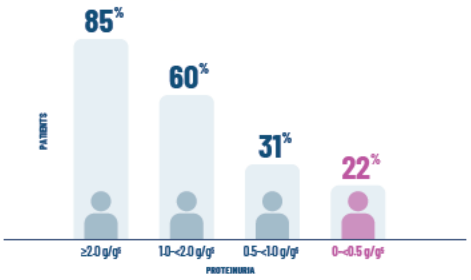
Please see additional Important Safety Information throughout, including BOXED WARNING, and full Prescribing Information.

Achieving complete remission of proteinuria (defined as <0.3 g/day) drives long-term nephroprotective benefits[5,6]

FILSPARI® (sparsentan) tablets 200 mg/400 mg

Any amount of proteinuria above 0.3 g/d drives irreversible nephron loss and accelerates progression to kidney failure[5,6]

RaDaR: patients progressing to kidney failure within 10 years of IgAN diagnosis*†‡



*When it comes to proteinuria, **don't settle for more**[5,6]*

This analysis received funding from Travere Therapeutics. All instances of proteinuria refer to time-averaged proteinuria, defined as the time-weighted averages for UPCR.

*The adult patient subpopulation assessed is representative of an incident population, examining time-averaged proteinuria over follow-up without requirement for a baseline UPCR at diagnosis.[5]

†Kidney failure was defined as the first occurrence of either long-term kidney replacement therapy, a confirmed eGFR of <15 mL/min/1.73 m², or CKD stage 5.[5]

‡The 10-year cohort included ~2400 patients.[5]

§UPCR 0.88 g/g = 1 g/d.[5]

CKD=chronic kidney disease; eGFR=estimated glomerular filtration rate; IgAN=immunoglobulin A nephropathy; RaDaR+UK: National Registry of Rare Kidney Diseases; UPCR=urine protein-to-creatinine ratio.

IMPORTANT SAFETY INFORMATION (cont'd): Contraindications

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

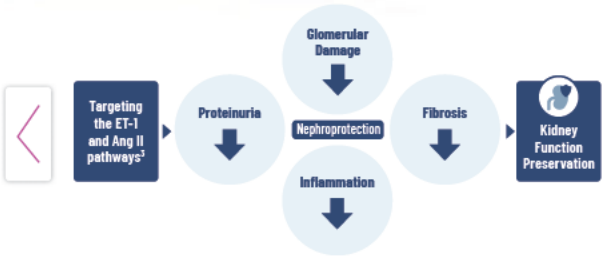
Please see additional Important Safety Information throughout, including BOXED WARNING, and full Prescribing Information.

Consistent nephroprotection. One molecule. Two targets.[2,3]

FILSPARI® (sparsentan) tablets 200 mg/400 mg

Simultaneously blocks the ET-1 and Ang II pathways to help protect the glomerulus[2,3]

ET-1 and Ang II are 2 key pathways
contributing to a cycle of kidney injury in IgAN[2-9]



*FILSPARI® is a non-immunosuppressive **D**ual **E**ndothelin **A**ngiotensin **R**eceptor **A**ntagonist **(DEARA)**[1]*

Ang II=angiotensin II; ET-1=endothelin-1; IgAN=immunoglobulin A nephropathy.

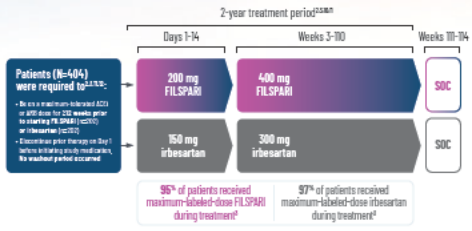
IMPORTANT SAFETY INFORMATION (cont'd): Warnings and Precautions

- **Hepatotoxicity:** Elevations in ALT or AST of at least 3-fold ULN have been observed in up to 3.5% of FILSPARI-treated patients, including cases confirmed with rechallenge.

Please see additional Important Safety Information throughout, including BOXED WARNING, and full Prescribing Information.

PROTECT: the 2-year superiority trial that studied FILSPARI® vs maximum-labeled-dose RASi[2,3]

FILSPARI® (sparsentan) tablets 200 mg/400 mg



Baseline mean eGFR[2]:
57 mL/min/1.73 m²

Geometric mean UPCR[2]:
1.2 g/g

Proteinuria at baseline[19]	FILSPARI n=202	irbesartan n=202
<0.80 g/g	24%	27%
≥0.80 to <1.25 g/g	25%	25%
≥1.25 to <1.80 g/g	24%	22%
≥1.80 g/g	25%	19%

ACEi=angiotensin-converting enzyme inhibitor; ARB=angiotensin II receptor blocker; eGFR=estimated glomerular filtration rate; RASi=renin-angiotensin system inhibitor; SOC=standard of care; UPCR=urine protein-to-creatinine ratio.

IMPORTANT SAFETY INFORMATION: Warnings and Precautions (cont'd)

- **Hepatotoxicity (cont'd):** While no concurrent elevations in bilirubin >2-times ULN or cases of liver failure were observed in FILSPARI-treated patients in clinical trials, some ERAs have caused elevations of aminotransferases, hepatotoxicity, and liver failure. To reduce the risk of potential serious hepatotoxicity, measure serum aminotransferase levels and total bilirubin prior to initiation of treatment and then every 3 months during treatment.

Please see additional Important Safety Information throughout, including BOXED WARNING, and full Prescribing Information.

Once-daily oral dosing for long-term use[2]

FILSPARI® (sparsentan) tablets 200 mg/400 mg

DAYS 1-14

200 mg

Start treatment with FILSPARI® at 200 mg orally once daily

200 mg

DAYS 15+

400 mg

After 14 days, increase to the recommended dose of 400 mg orally once daily, as tolerated

400 mg

Per the Prescribing Information, the only treatments contraindicated with FILSPARI are ARBs, ERAs, and aliskiren[2]

97% ***of patients taking FILSPARI did not require rescue immunosuppressive treatment during the double-blind phase.*** *Rescue immunosuppression was allowed during PROTECT[2]*

~98% *of real-world FILSPARI patients continue on therapy every month[1,a]*

*Data on file (as of March 2026). Travere Therapeutics, Inc.

Pills not shown at actual size.

ARB=angiotensin II receptor blocker; ERA=endothelin receptor antagonist.

IMPORTANT SAFETY INFORMATION: Warnings and Precautions (cont'd)

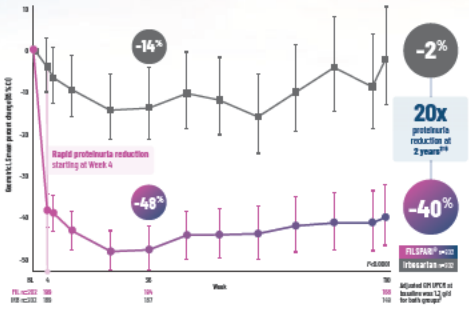
- **Hepatotoxicity (cont'd):** Advise patients with symptoms suggesting hepatotoxicity (nausea, vomiting, right upper quadrant pain, fatigue, anorexia, jaundice, dark urine, fever, or itching) to immediately stop treatment with FILSPARI and seek medical attention. If aminotransferase levels are abnormal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

Please see additional Important Safety Information throughout, including BOXED WARNING, and full Prescribing Information.

Proven to achieve rapid, superior, and sustained proteinuria reduction over 2 years[2,3,15]

FILSPARI® (sparsentan) tablets 200 mg/400 mg

Percent reduction in proteinuria from baseline through Week 110



*FILSPARI delivered **consistent proteinuria reduction** regardless of baseline UPCR[2,3]**

*At baseline, the geometric mean UPCR was 1.2 g/g with a standard deviation range of 0.8 g/g-1.8 g/g.[2,3]

BL=baseline; CI=confidence interval; GM=geometric mean; LS=least squares; UPCR=urine protein-to-creatinine ratio.

IMPORTANT SAFETY INFORMATION: Warnings and Precautions (cont'd)

- **Hepatotoxicity (cont'd):** 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) because monitoring hepatotoxicity in these patients may be more difficult and these patients may be at increased risk for serious hepatotoxicity.

Please see additional Important Safety Information throughout, including BOXED WARNING, and full Prescribing Information.

Proven to drive 3x more patients to complete remission of proteinuria (<0.3 g/day)[3,16]*

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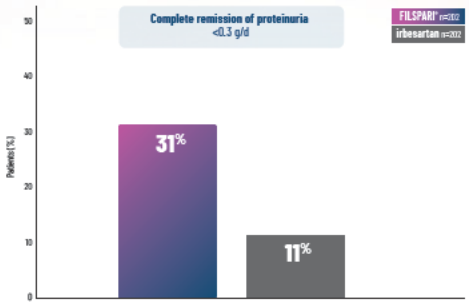
Prespecified exploratory analysis: percentage of patients with complete remission of proteinuria at any time during treatment in the double-blind period[3,10,16]



*Complete remission of proteinuria is measured by reaching urinary protein excretion <0.3 g/d at any time on FILSPARI during the 110-week study compared to those taking irbesartan.[3]

IMPORTANT SAFETY INFORMATION: Warnings and Precautions (cont'd)

- **FILSPARI REMS:** Due to the risk of hepatotoxicity, FILSPARI is available only through a restricted program called the FILSPARI REMS. Prescribers, patients, and pharmacies must be enrolled in the REMS program and comply with all requirements (www.filsparirems.com).

Please see additional Important Safety Information throughout, including BOXED WARNING, and full Prescribing Information.

Proven to achieve better kidney function preservation over 2 years[2]*

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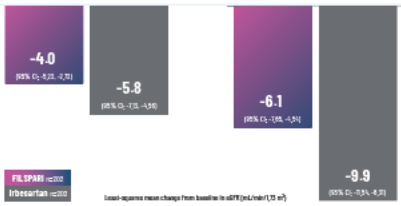
eGFR benefit with FILSPARI* increased over time[2,17]:

+1.9
difference at Year 1 (Week 58)

+3.8
difference at Year 2 (Week 110)



FILSPARI achieved the slowest rate of eGFR decline in any Phase 3 IgAN trial[2,17]

*At baseline, 404 patients were randomized to either FILSPARI (n=202) or irbesartan (n=202). At Week 58, there were 188 patients still taking FILSPARI and 173 taking irbesartan. At Week 110, there were 171 taking FILSPARI and 155 taking irbesartan.[2,17]

CI=confidence interval; eGFR=estimated glomerular filtration rate; IgAN=immunoglobulin A nephropathy.

IMPORTANT SAFETY INFORMATION: Warnings and Precautions (cont'd)

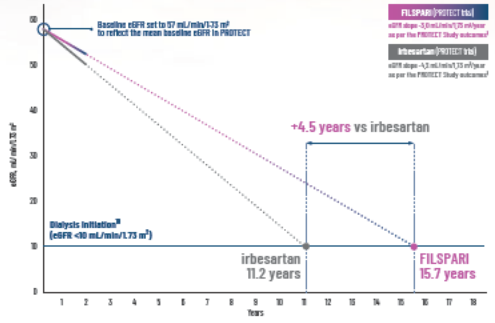
- **Embryo-Fetal Toxicity:** Based on data from animal reproduction studies, FILSPARI may cause fetal harm when administered to a pregnant patient and is contraindicated during pregnancy. The available human data for ERAs do not establish the presence or absence of fetal harm related to the use of FILSPARI.

Please see additional Important Safety Information throughout, including BOXED WARNING, and full Prescribing Information.

Extrapolated data suggest FILSPARI® may provide longer term benefits for patients[2,10]

FILSPARI® (sparsentan) tablets 200 mg/400 mg

Potential long-term impact of preserved eGFR slope



eGFR=estimated glomerular filtration rate.

IMPORTANT SAFETY INFORMATION: Warnings and Precautions (cont'd)

- **Embryo-Fetal Toxicity (cont'd):** Counsel patients who can become pregnant of the potential risk to a fetus. Exclude pregnancy before initiating treatment with FILSPARI. Advise patients who can become pregnant to use effective contraception prior to initiation of treatment, during treatment, and for two weeks after discontinuation of treatment with FILSPARI. Advise pre-pubertal females and/or their guardian(s) of the fetal risk and the need to use effective contraception once they reach reproductive potential. When pregnancy is detected, discontinue FILSPARI as soon as possible.

Please see additional Important Safety Information throughout, including BOXED WARNING, and full Prescribing Information.

FILSPARI® was well tolerated over 2 years[2,3]

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Patients with TEAEs, n (%)	FILSPARI (n=202) n (%)	irbesartan (n=202) n (%)
Hyperkalemia[a]	34 (17)	27 (13)
Hypotension (including orthostatic hypotension)	33 (16)	13 (6)
Peripheral edema[a]	33 (16)	29 (14)
Dizziness[a]	32 (16)	14 (7)
Anemia	16 (8)	9 (4)
Acute kidney injury	12 (6)	5 (2)
Transaminase elevations[b]	7 (3.5)	8 (4.0)
TEAEs leading to treatment discontinuation	21 (10)	18 (9)

*Comparably **low incidences of TEAEs** leading to discontinuation of treatment*[3]

***No drug-induced liver injury** following treatment with FILSPARI. Comparably low incidences of ALT/AST >3x ULN*[3]

***No severe cases of edema or associated discontinuations** for patients on FILSPARI*[3]

***Low rates of treatment discontinuation due to hypotension** with FILSPARI (1%)*[3]

[a]Includes related terms.[2]
[b]Elevations in ALT or AST >3-fold ULN.[2]

ALT=alanine transaminase; AST=aspartate transaminase; TEAE=treatment-emergent adverse event; ULN=upper limit of normal.

IMPORTANT SAFETY INFORMATION: Warnings and Precautions (cont'd)

- **Hypotension:** Hypotension has been observed in patients treated with ARBs and ERAs and was observed in FILSPARI clinical studies. 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, despite elimination or reduction of other antihypertensive medications, consider a dose reduction or dose interruption of FILSPARI. A transient hypotensive response is not a contraindication to further dosing of FILSPARI, which can be given once blood pressure has stabilized.

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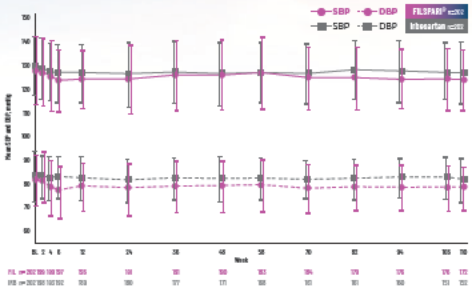
Blood pressure remained consistent over a 2-year period and was comparable to irbesartan[10]

FILSPARI® (sparsentan) tablets 200 mg/400 mg



- At Week 110, the mean change from baseline in SBP was -3.8 mmHg (95% CI: -5.5, -2.1) in the FILSPARI group and -2.5 mmHg (95% CI: -4.3, -0.8) in the irbesartan group[3]
- At Week 110, the mean change from baseline in DBP was -3.4 mmHg (-4.6 to -2.2) in the FILSPARI group and -1.2 mmHg (-2.5 to 0.0) in the irbesartan group[3]
- Hypotension has been observed in clinical studies with FILSPARI (16%), with a greater incidence of hypotension-associated adverse events compared to irbesartan (6%). Some were serious, including dizziness (16% vs 7%)[2]

Reprinted from *The Lancet*, Vol. 402, Rovin BH, Barratt J, Heerspink HJL, et al., Efficacy and safety of sparsentan versus irbesartan in patients with IgA nephropathy (PROTECT): 2-year results from a randomised, active-controlled, phase 3 trial [supplementary appendix], Page 15, Copyright 2023, with permission from Elsevier.

BL=baseline; CI=confidence interval; DBP=diastolic blood pressure; SBP=systolic blood pressure.

IMPORTANT SAFETY INFORMATION: Warnings and Precautions (cont'd)

- **Acute Kidney Injury:** Monitor kidney function periodically. Drugs that inhibit the renin-angiotensin system (RAS) can cause kidney injury. Patients whose kidney function may depend in part on the activity of the RAS (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.

Please see additional Important Safety Information throughout, including BOXED WARNING, and full Prescribing Information.

Safety considerations and guidance[2]

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Risk Evaluation and Mitigation Strategy (REMS) program

FILSPARI® is available only through a restricted program called the FILSPARI REMS because of the risk of hepatotoxicity.

- Monitoring requirement: Measure aminotransferase levels and total bilirubin before initiating FILSPARI and every 3 months during treatment with FILSPARI
- Prescribers, patients, and pharmacies must be enrolled in the REMS program and comply with all requirements (www.filsparirems.com)

Embryo-fetal toxicity

- Exclude pregnancy before initiating treatment with FILSPARI
- Advise use of effective contraception prior to initiation, during, and for 2 weeks after discontinuation of treatment with FILSPARI; discontinue FILSPARI if patient becomes pregnant
- Educate patients on the use of emergency contraception in the event of unprotected sex or contraceptive failure

IMPORTANT SAFETY INFORMATION: Warnings and Precautions (cont'd)

- **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.

Please see additional Important Safety Information throughout, including BOXED WARNING, and full Prescribing Information.

FILSPARI® (sparsentan) tablets 200 mg/400 mg

For adults with IgA nephropathy

FILSPARI®: a stronger foundation for kidney preservation[2]

- FILSPARI is a **non-immunosuppressive Dual Endothelin Angiotensin Receptor Antagonist**[1,3]
- Proven to **achieve rapid, superior, and sustained proteinuria reduction** vs maximum-labeled-dose RASi[2,3]
- Proven to drive **3x more patients to complete remission of proteinuria**[3,16]
- Proven to achieve **better kidney function preservation**[2]
- **Well tolerated over 2 years,** with discontinuations comparable to maximum-labeled-dose irbesartan[2,3]
- FILSPARI is **only available through the FILSPARI REMS** due to hepatotoxicity risk and **carries a Boxed Warning** for hepatotoxicity and embryo-fetal toxicity[2]
- **Once-daily oral dosing** for long-term use[2]

Included in ***KDIGO 2025 Guideline***[1]

The #1 most prescribed FDA-approved treatment for IgAN*

*Source: Komodo Claims, total Rx data through 11/2025.[4]

IgA=immunoglobulin A; IgAN=immunoglobulin A nephropathy; KDIGO=Kidney Disease: Improving Global Outcomes; RAS=renin-angiotensin system; RASi=renin-angiotensin system inhibitor; REMS=Risk Evaluation and Mitigation Strategy.

IMPORTANT SAFETY INFORMATION: Warnings and Precautions (cont'd)

- **Fluid Retention:** Fluid retention may occur with ERAs and has been observed in clinical studies with FILSPARI. FILSPARI has not been evaluated in patients with heart failure. If clinically significant fluid retention develops, evaluate the patient to determine the cause and the potential need to initiate or modify the dose of diuretic treatment then consider modifying the dose of FILSPARI.

Please see additional Important Safety Information throughout, including BOXED WARNING, and full Prescribing Information.

Important Safety Information

FILSPARI® (sparsentan) tablets 200 mg/400 mg

INDICATIONS & USAGE

FILSPARI® (sparsentan) is indicated to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: HEPATOTOXICITY AND EMBRYO-FETAL TOXICITY

Because of the risk of hepatotoxicity, 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 3.5% of FILSPARI-treated patients, including cases confirmed with rechallenge.

Measure transaminases and bilirubin before initiating treatment 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 is contraindicated for use during pregnancy because it may cause fetal harm if used by pregnant patients. Therefore, in patients who can become pregnant, exclude pregnancy prior to initiation of FILSPARI. Advise use of effective contraception before the initiation of treatment, during treatment, and for two weeks after discontinuation of treatment with FILSPARI. When pregnancy is detected, discontinue FILSPARI as soon as possible.

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 in up to 3.5% of FILSPARI-treated patients, including cases confirmed with rechallenge. While no concurrent elevations in bilirubin >2-times ULN or cases of liver failure were observed in FILSPARI-treated patients in clinical trials, some ERAs have caused elevations of aminotransferases, hepatotoxicity, and liver failure. To reduce the risk of potential serious hepatotoxicity, measure serum aminotransferase levels and total bilirubin prior to initiation of treatment and 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) because monitoring hepatotoxicity in these patients may be more difficult and these patients may be at increased risk for serious hepatotoxicity.

Important Safety Information

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Warnings and Precautions (cont'd)

- **FILSPARI REMS:** Due to the risk of hepatotoxicity, FILSPARI is available only through a restricted program called the FILSPARI REMS. Prescribers, patients, and pharmacies must be enrolled in the REMS program and comply with all requirements (www.filsparirems.com).
- **Embryo-Fetal Toxicity:** Based on data from animal reproduction studies, FILSPARI may cause fetal harm when administered to a pregnant patient and is contraindicated during pregnancy. The available human data for ERAs do not establish the presence or absence of fetal harm related to the use of FILSPARI. Counsel patients who can become pregnant of the potential risk to a fetus. Exclude pregnancy before initiating treatment with FILSPARI. Advise patients who can become pregnant to use effective contraception prior to initiation of treatment, during treatment, and for two weeks after discontinuation of treatment with FILSPARI. Advise pre-pubertal females and/or their guardian(s) of the fetal risk and the need to use effective contraception once they reach reproductive potential. When pregnancy is detected, discontinue FILSPARI as soon as possible.
- **Hypotension:** Hypotension has been observed in patients treated with ARBs and ERAs and was observed in FILSPARI clinical studies. 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, despite elimination or reduction of other antihypertensive medications, consider a dose reduction or dose interruption of FILSPARI. A transient hypotensive response is not a contraindication to further dosing of FILSPARI, which can be given once blood pressure has stabilized.
- **Acute Kidney Injury:** Monitor kidney function periodically. Drugs that inhibit the renin-angiotensin system (RAS) can cause kidney injury. Patients whose kidney function may depend in part on the activity of the RAS (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 in clinical studies with FILSPARI. FILSPARI has not been evaluated in patients with heart failure. If clinically significant fluid retention develops, evaluate the patient to determine the cause and the potential need to initiate or modify the dose of diuretic treatment then consider modifying the dose of FILSPARI.

Adverse Reactions

- **IgAN patients receiving FILSPARI:** The most common adverse reactions (≥5%) are hyperkalemia, hypotension (including orthostatic hypotension), peripheral edema, dizziness, anemia, and acute kidney injury.

Drug Interactions

- **Renin-Angiotensin System (RAS) Inhibitors and ERAs:** Do not coadminister FILSPARI with ARBs, ERAs, or aliskiren due to increased risks of hypotension, syncope, hyperkalemia, and changes in renal function (including acute renal failure).
- **Strong and Moderate CYP3A Inhibitors:** Avoid concomitant use of FILSPARI with strong CYP3A inhibitors. If a strong CYP3A inhibitor cannot be avoided, interrupt FILSPARI treatment. When resuming treatment with FILSPARI, consider dose titration. Monitor blood pressure, serum potassium, edema, and kidney function regularly when used concomitantly with moderate CYP3A inhibitors. Concomitant use with a strong CYP3A inhibitor increases sparsentan exposure which may increase the risk of FILSPARI adverse reactions.

Important Safety Information

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Drug Interactions (cont'd)

- **Strong CYP3A Inducers:** Avoid concomitant use with a strong CYP3A inducer. Concomitant use with a strong CYP3A inducer decreases sparsentan exposure which may reduce FILSPARI efficacy.
- **Non-Steroidal Anti-Inflammatory Agents (NSAIDs), Including Selective Cyclooxygenase-2 (COX-2) Inhibitors:** Monitor for signs of worsening renal function with concomitant use with NSAIDs (including selective COX-2 inhibitors). In patients with volume depletion (including those on diuretic therapy) or with impaired kidney function, concomitant use of NSAIDs (including selective COX-2 inhibitors) with drugs that antagonize the angiotensin II receptor may result in deterioration of kidney function, including possible kidney failure. These effects are usually reversible.
- **CYP2B6, 2C9, and 2C19 Substrates:** Monitor for efficacy of concurrently administered CYP2B6, 2C9, and 2C19 substrates and consider dosage adjustment in accordance with the Prescribing Information. Sparsentan is a weak inducer of CYP2B6 and 2C9, and a moderate inducer of 2C19. Sparsentan decreases exposure of these substrates, which may reduce efficacy related to these substrates.
- **P-gp Substrates:** Monitor for adverse reactions and consider dose reduction of P-gp substrates with narrow therapeutic indices when co-administered with FILSPARI. FILSPARI is a weak P-gp inhibitor and may increase plasma concentrations of P-gp substrate drugs.
- **Agents Increasing Serum Potassium:** Monitor serum potassium frequently in patients treated with FILSPARI and other agents that increase serum potassium. 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.

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

References

FILSPARI® (sparsentan) tablets 200 mg/400 mg

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