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FILSPARI®▼ (sparsentan) is included in the KDIGO 2025 guidelines

for the management of IgA nephropathy (IgAN) in patients at risk of progressive kidney failure[1]

Explore how the KDIGO 2025 guidelines redefine IgAN management, including the role of FILSPARI in treatment[1]



Prescribing information and adverse event reporting information can found on the back of this leaflet.

FILSPARI is indicated for the treatment of adults with primary IgAN with a urine protein excretion (UPE) ≥1.0 g/day (or urine protein-to-creatinine ratio (UP/C) ≥0.75 g/g)[2]

▼ This medicine is subject to additional monitoring.

CSL

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FILSPARI® ▼ (sparsentan) tablets 200 mg/400 mg

The KDIGO 2025 guidelines emphasise the need to reduce proteinuria in patients with IgAN[1]

Patients are considered at **risk of progressive loss of kidney function** if they have **proteinuria ≥0.5 g/day** while on or off treatment for IgAN[1]

Updated kidney biopsy threshold:[1]

IgAN can only be diagnosed with a kidney biopsy; to ensure early diagnosis and prompt treatment, **a kidney biopsy should be considered in all adults with proteinuria ≥0.5 g/day in whom IgAN is a possible diagnosis and kidney biopsy is not contraindicated**

Newly defined IgAN treatment goals:[1]



To maintain **UPE** at **<0.5 g/day,** and **ideally <0.3 g/day***



To reduce the rate of **loss of kidney function to <1 mL/min/year** for the rest of the patient's life

The 2 key dimensions of IgAN management:[1]

Simultaneous focus on



Preventing or reducing IgA immune complex (IgA-IC) formation and immune complex-mediated glomerular injury



Managing the consequences of existing IgAN-induced nephron loss

*In some patients with extensive kidney scarring this may not be possible and multiple treatment strategies are likely to be needed to achieve this.[1]

FILSPARI is recognised by KDIGO 2025[1]

The KDIGO 2025 guidelines recognise the ability of **FILSPARI, the first and only dual endothelin angiotensin receptor antagonist (DEARA),** to reduce proteinuria and slow the progression of kidney disease through dual inhibition of the endothelin and angiotensin pathways[1,3,4]

KDIGO recommendation 1.4.4.2

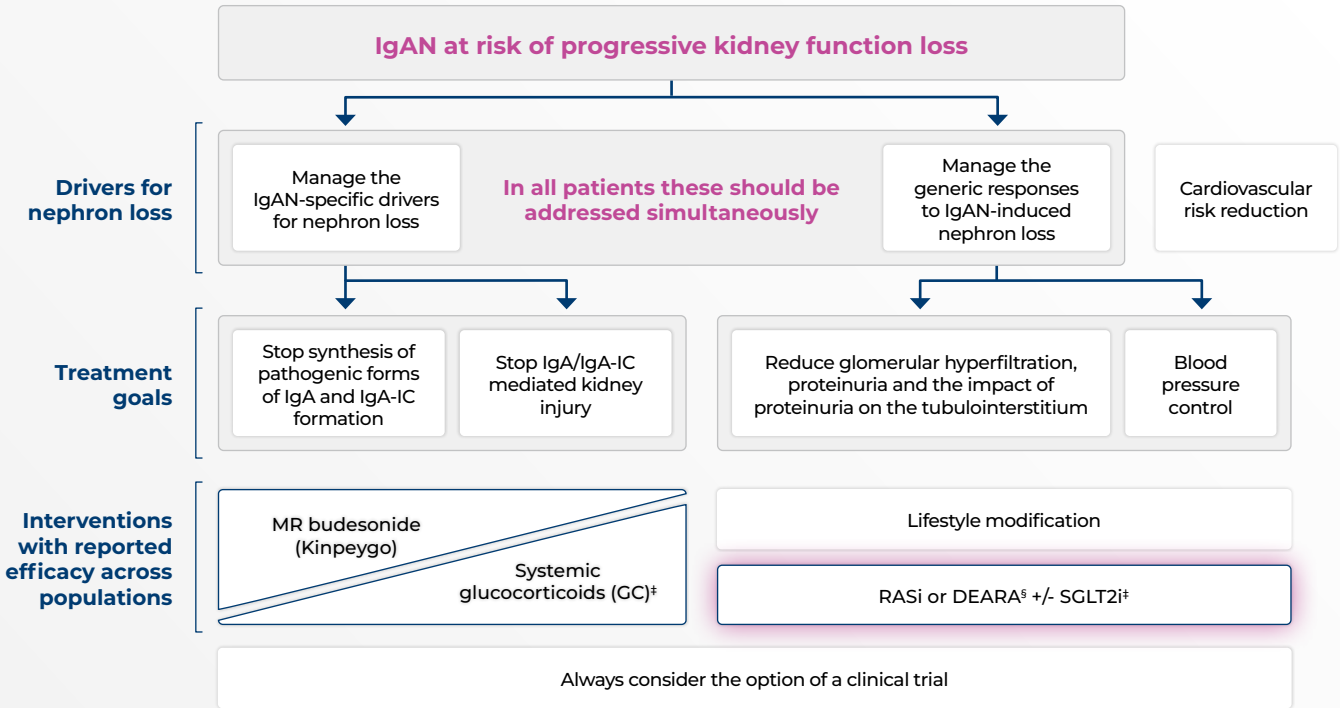
We suggest that patients who are at risk of progressive kidney function loss with IgAN be treated with FILSPARI (2B)[1]

Practice point 1.4.4.3

FILSPARI is a DEARA and should not be prescribed together with RASi[1†]

†Coadministration of FILSPARI with angiotensin receptor blockers (ARBs), endothelin receptor antagonist (ERAs), or renin inhibitors is contraindicated.[2]

KDIGO 2025 treatment targets in IgAN and the positioning of drugs included in the guidelines



‡Systemic GCs and SGLT2i are not licensed in Ireland for the treatment of IgAN. §FILSPARI is indicated for the treatment of adults with primary IgAN with a UPE ≥1.0 g/day (Or UP/C ≥0.75 g/g).[2]

Adapted from KDIGO. 2025

> **"The observed greater proteinuria reduction and eGFR preservation with combined dual blockade of the renin-angiotensin and endothelin systems via a DEARA suggest that this approach may be an appropriate first-line approach to manage the responses of IgAN-induced nephron loss in contrast to the RASi-first approach."[1]**

FILSPARI important safety information

The most commonly reported adverse drug reactions with FILSPARI were hypotension (10.8 %), hyperkalaemia (9.6 %), dizziness (7.8 %), and oedema peripheral (5.4 %). The most common serious adverse reaction reported was acute kidney injury (0.9 %).[2]

FILSPARI treatment must only be initiated in women of childbearing potential when the absence of pregnancy has been verified and effective contraception is practised. Women of childbearing potential have to use effective contraception during and up to 1 month after treatment has stopped.[2]

Liver function should be monitored prior to initiation of treatment and then continue monitoring every 3 months. Avoid initiation of FILSPARI in patients with elevated aminotransferases (> 2 × ULN). Discontinue in patients with sustained, unexplained, clinically significant elevated aminotransferases, with or without elevated bilirubin (> 2 × ULN), or accompanied by signs and symptoms of hepatic injury.[2]

Refer to the SmPC for full safety information before prescribing

Scan here to explore the full 2025 KDIGO guidelines

By scanning the QR code, you will be going to a third party site

Key considerations for implementation of FILSPARI:

- FILSPARI, as a DEARA, should not be prescribed together with RASi, because FILSPARI already combines RASi with an endothelin antagonist in a single molecule[1]
- There is no need for a washout period when initiating FILSPARI[4]

References and Abbreviations: ARB, angiotensin II receptor blocker; **DEARA,** dual endothelin angiotensin receptor antagonist; **eGFR,** estimated glomerular filtration rate; **ERA,** endothelin receptor antagonist; **GC,** glucocorticoid; **HCP,** healthcare professional; **IgA,** immunoglobulin A; **IgA-IC,** immunoglobulin A immune complexes; **IgAN,** immunoglobulin A nephropathy; **KDIGO,** Kidney Disease: Improving Global Outcomes; **MR,** modified release; **RASi,** renin-angiotensin system inhibitor; **SGLT2i,** sodium-glucose co-transporter 2 inhibitor; **ULN,** upper limit of normal; **UP/C,** urine protein-to-creatinine ratio; **UPE,** urine protein excretion.

1. Kidney Disease: Improving Global Outcomes (KDIGO) IgAN and IgAV Work Group. *Kidney Int.* 2025;108(4S):S1–S71. **2.** FILSPARI EU SmPC. Last accessed: October 2026. **3.** Syed YY, *et al. Drugs.* 2023;83(6):563–8. **4.** Campbell KN, *et al. Int J Nephrol Renovasc Dis.* 2023;16:281–91.

Filspari ▼ (sparsentan) Prescribing Information – Republic of Ireland

For full prescribing information refer to the Summary of Product Characteristics (SmPC)
Active ingredient: Sparsentan
Presentation: Film-coated tablets as 200mg or 400mg. Indication: Filspari is indicated for the treatment of adults with primary immunoglobulin A nephropathy (IgAN) with a urine protein excretion ≥1.0 g/day (or urine protein-to-creatinine ratio ≥0.75 g/g).
Dosage and Administration: Initiate at a dose of 200 mg once daily for 14 days and then increase to a maintenance dose of 400 mg once daily, dependent upon tolerability. If patients experience tolerability issues (systolic blood pressure [SBP] ≤100 mmHg, diastolic blood pressure ≤60 mmHg, worsening oedema, or hyperkalaemia), adjustment of concomitant medicinal products, followed by temporary down-titration or discontinuation of Filspari is recommended. When resuming treatment with Filspari after interruption, repeating the initial dosing schedule may be considered. Interruption of treatment preceded, or not, by dose reduction of Filspari may be considered based on persisting hypotension or changes in liver function. For oral use. Recommended to swallow whole with water.
Special populations: Elderly: No dose adjustment is recommended. The increase to a maintenance dose of 400 mg once daily should be performed with caution, based on tolerability. **Hepatic impairment:** No dose adjustment recommended in patients with mild or moderate hepatic impairment. There is limited experience in patients with moderate hepatic impairment, therefore use with caution. Sparsentan has not been studied in patients with severe hepatic impairment, therefore is not recommended for use. Due to limited of clinical experience, Filspari should not be initiated in patients with AST or ALT >2 x ULN. **Renal impairment:** No dose adjustment is required in patients with mild chronic kidney disease (CKD) stage 2 (eGFR 60-89 mL/min/1.73 m²) or moderate CKD stages 3a and 3b (eGFR 30-59 mL/min/1.73 m²). As there is limited clinical experience in patients with severe kidney disease, sparsentan is not recommended in these patients. **Kidney transplant:** Sparsentan has not been studied in patients who have received a kidney transplant, therefore sparsentan should be used with caution is these patients. **Dialysis:** Sparsentan has not been studied in patients undergoing dialysis, therefore initiation is not recommended. **Children:** The safety and efficacy of Filspari in children below the age of 18 years with IgAN have not yet been established. No data are available. **Pregnancy:** Sparsentan treatment must only be initiated in women of childbearing potential when the absence of pregnancy has been verified. Exclude pregnancy before, during and for 1 month after treatment with sparsentan has stopped. The frequency of recommended pregnancy testing should be determined by the method of contraception used and the associated likelihood of contraceptive failure. Women of childbearing potential have to use effective contraception during and up to 1 month after treatment has stopped. Filspari is contraindicated during pregnancy. **Breastfeeding:** Sparsentan should not be used during breastfeeding.
Contraindications: Filspari is contraindicated in patients with hypersensitivity to sparsentan or to any of its excipients. Filspari is contraindicated during pregnancy. Do not co-administer Filspari with angiotensin receptor blockers, endothelin receptor antagonists, or renin inhibitors
Special warnings and precautions:
Women of childbearing potential: Filspari treatment must only be initiated in women of childbearing potential when the absence of pregnancy has been verified and effective contraception is practised. Exclude pregnancy before, during and for 1 month after treatment with sparsentan has stopped. The frequency of recommended pregnancy testing should be determined by the method of contraception used and the associated likelihood of contraceptive failure. Women of childbearing potential have to use effective contraception during and up to 1 month after treatment has stopped. Filspari is contraindicated during pregnancy. **Hypotension:** Hypotension may occur during Filspari treatment, and is more frequently reported in elderly patients. In patients at risk for hypotension, eliminating or adjusting other antihypertensive medicinal products and maintaining appropriate volume status should be considered. If hypotension develops despite elimination or reduction of other antihypertensive medicinal products, dose reduction or dose interruption of Filspari should be considered. A transient hypotensive response is not a contraindication to further dosing of Filspari; treatment can be resumed once BP has stabilised. If hypotension persists despite elimination or reduction of antihypertensive medicinal products, sparsentan dosing should be reduced to the initial starting dose until BP stabilises. Dose interruption of treatment with sparsentan should be considered if symptoms of hypotension persist after 2 weeks of dose reduction. Sparsentan should be used with caution in patients with SBP values ≤ 100 mmHg. Sparsentan should not be uptitrated in patients with SBP values ≤ 100 mmHg. **Impaired kidney function:** A transient increase in serum creatinine may occur, especially during treatment initiation. Periodic monitoring of serum creatinine and serum potassium levels should be performed in patients at risk. Filspari should be used with caution in patients with bilateral renal artery stenosis. Filspari is not recommended in patients with an estimated glomerular filtration rate (eGFR) <30 mL/min/1.73m². **Fluid retention:** Fluid retention has been associated with medicinal products that antagonise the endothelin type A receptor, including Filspari. If fluid retention develops, treatment with diuretics is recommended, or the dose of existing diuretics should be increased before modifying the dose of Filspari. Consider diuretic treatment in patients with existing fluid retention prior to initiation of Filspari. Filspari has not been studied in patients with heart failure, therefore should be used with caution. **Liver function:** Elevations in ALT or AST of at least 3 x ULN have been observed with Filspari. No concurrent elevations in bilirubin >2 x ULN or cases of liver failure have been observed in Filspari-treated patients. To reduce the risk of potential serious hepatotoxicity, serum aminotransferase levels and total bilirubin should be monitored prior to initiation of treatment and then every 3 months. Patients should be monitored for signs of hepatic injury. If patients develop sustained, unexplained, clinically significant ALT and/or AST elevation, or if elevations are accompanied by an increase in bilirubin >2 × ULN, or if ALT and/or AST elevation is accompanied by signs or symptoms of hepatic injury (e.g. jaundice), Filspari therapy should be discontinued. Consider re-initiation of Filspari only when hepatic enzyme levels and bilirubin return to pretreatment values and only in patients without clinical symptoms of hepatotoxicity. Avoid initiation of sparsentan in patients with elevated aminotransferase (> 2 × ULN) prior to drug initiation. There is limited clinical experience with moderate hepatic impairment, therefore, use with caution. **Dual blockade of the Renin-angiotensin-aldosterone system (RAAS):** Dual blockade of RAAS through the combined use of ACE inhibitors, angiotensin II receptor blockers (partly a mechanism of sparsentan) or renin inhibitors is not recommended. If dual blockade therapy is considered absolutely necessary, this should only occur under specialist supervision and subject to frequent close monitoring of renal function, electrolytes and BP. **Hyperkalaemia:** Treatment should not be initiated in patients with serum potassium level > 5.5 mmol/l. As with other medicinal products that affect the RAAS, hyperkalaemia may occur during the treatment with sparsentan, especially in the presence of renal impairment and/or heart failure. Close monitoring of serum potassium in patients at risk is recommended. If patients experience clinically significant hyperkalaemia adjustment of concomitant medicinal products, or temporary down–titration or discontinuation is recommended. If serum potassium level is > 5.5 mmol/l discontinuation should be considered. **Excipients:** Contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption should not take this medicinal product. Filspari contains less than 1 mmol sodium (23 mg) per tablet, and is essentially 'sodium-free'.
Overdose: Sparsentan has been administered in doses of up to 1600 mg/day in healthy subjects without evidence of dose limiting toxicities. Patients who experience overdose (possibly experiencing signs and symptoms of hypotension) should be monitored closely and appropriate symptomatic treatment given.
Undesirable effects: Very common (≥ 1/10): Hypotension. Common (≥ 1/100 to < 1/10): hyperkalaemia, dizziness, headache, orthostatic hypotension, renal impairment, acute kidney injury, peripheral oedema, fatigue, blood creatinine increased, elevated transaminase. Uncommon (≥ 1/1,000 to < 1/100): anaemia.
Please consult the SmPC for further information on undesirable effects.
Legal category: POM
MA Number: EU/1/23/1788/001 (200mg tablet), EU/1/23/1788/002 (400mg tablet), EU/1/23/1788/003 (400mg tablet)
Date of authorisation: 19/04/2024
MA Holder: Vifor France, 100-101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris la Défense Cedex, France.
Document number: IE-SPT-2600010
Date of preparation: July 2026
Additional information is available on request.

▼ This medicine is subject to additional monitoring. Adverse events should be reported. Reporting forms and information can be found at http://www.hpra.ie/homepage/about-us/report-an-issue. Adverse events should also be reported to Vifor Fresenius Medical Care Renal Pharma, care of Vifor Pharma Ltd. Tel: + 441276 853633. E-mail: medicalinfo_UK@viforpharma.com