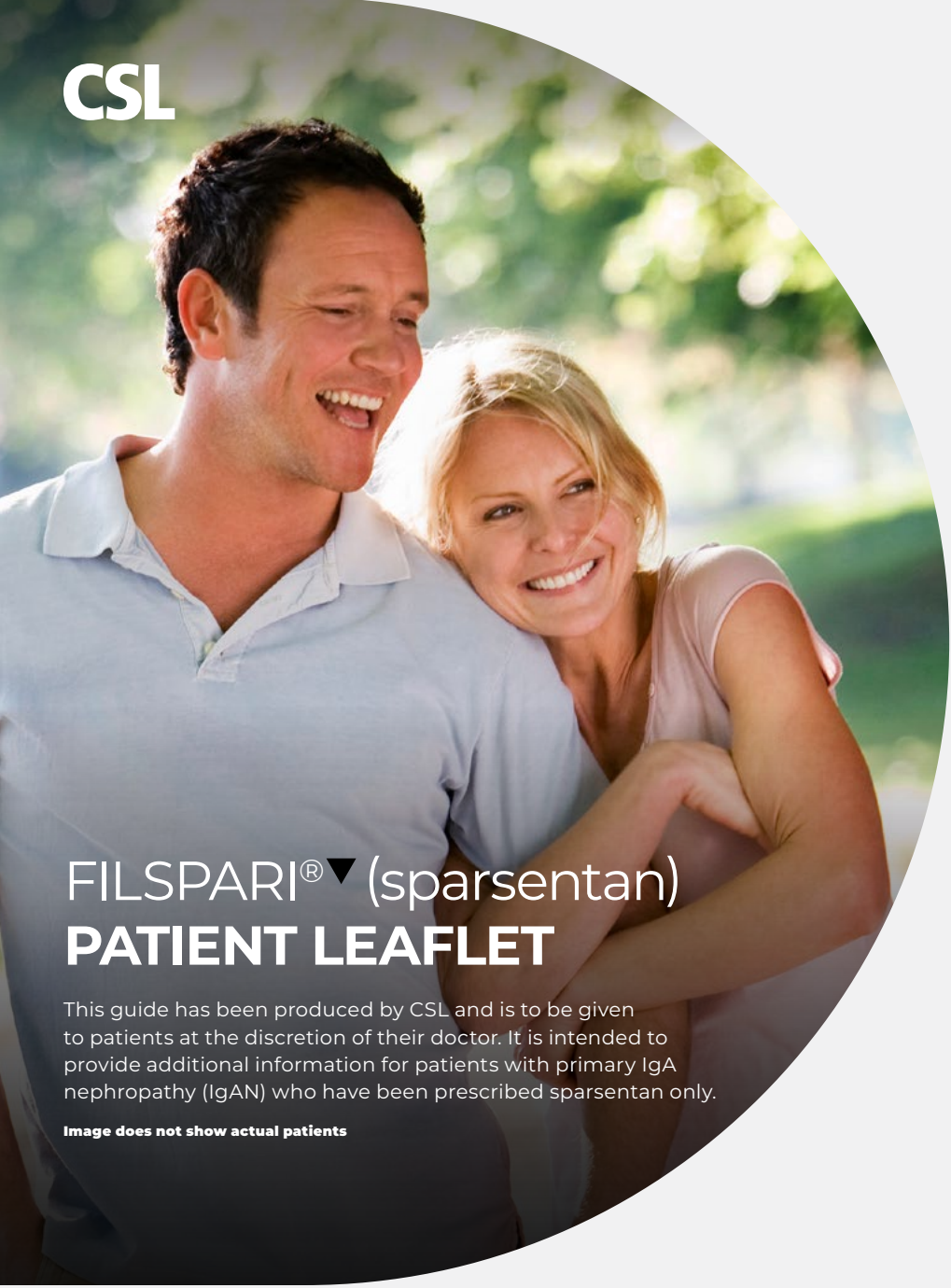


FILSPARI®▼ (sparsentan)
PATIENT LEAFLET

This guide has been produced by CSL and is to be given to patients at the discretion of their doctor. It is intended to provide additional information for patients with primary IgA nephropathy (IgAN) who have been prescribed sparsentan only.

Image does not show actual patients

This guide does not replace the patient information leaflet and patient card in the pack. Please always refer to the patient information leaflet before taking this medicine

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See page 9 or visit http://www.hpra.ie/homepage/about-us/report-an-issue for how to report side effects.

IE-SPT-2600019 | October 2026

What is IgAN?



Immunoglobulin A nephropathy (IgAN), also known as Berger's disease, is a rare kidney disease that, over time, can lead to kidney damage and loss of kidney function.[1,2] This occurs because the immune system (the body's natural defence system) produces a faulty version of an antibody called immunoglobulin A (IgA)[2]

The faulty antibody builds up into clusters that get stuck in the small blood vessels of the kidney, called glomeruli, which filter excess fluids and waste from the blood. This build-up damages the glomeruli, causing leakage of blood (haematuria) and protein into the urine, and progressive loss of kidney function[2]



Protein in the urine (proteinuria) is a key marker for disease progression, and too much proteinuria can cause damage to important kidney cells.[3] Two hormones, called endothelin (ET-1) and angiotensin (ANG II), play an important role in regulating processes in the kidney, such as inflammation, that lead to progression of kidney damage[2,4]

Elevated proteinuria levels may represent the progression of IgAN,so it is important to monitor and manage this to help maintain kidney health or slow disease progression[5]

About sparsentan

What is this medicine?

A once-daily tablet for the treatment of adults with primary IgAN with a urine protein excretion ≥1.0 g/day (or urine protein-to-creatinine ratio ≥0.75 g/g)[6,7]

How this medicine works

This medicine contains the active substance sparsentan[7]

It blocks the receptors (targets) of ET-1 and ANG II. By blocking these receptors, this medicine can lower the amount of protein that leaks into the urine and thereby may help to slow disease progression[7]

When you start treatment, your doctor may adjust or discontinue certain blood pressure-lowering medications you may be taking. This is because sparsentan should not be taken with other medicines that target the ANG II or ET-1 pathways, such as angiotensin receptor blockers, endothelin receptor blockers or renin inhibitors, many of which are used to treat high blood pressure[7]

Your doctor has prescribed you this medicine as your proteinuria levels are 1 g/day or above (or you have a urine protein-to-creatinine ratio ≥0.75 g/g)[7]

How will your response to your treatment be measured?

Your response to treatment is typically measured using several key indicators:

1. Proteinuria:
One of the primary goals of your treatment is to reduce the amount of protein present in your urine[8]

2. Kidney function:
This is often determined through blood tests that measure creatinine levels. From this, the estimated glomerular filtration rate (eGFR) can be calculated[9]

Your response indicators may also include other factors, such as haematuria and blood pressure[8]

What you should be aware of before taking sparsentan[7]



Talk to your doctor about your medical conditions, which may include low blood pressure, decreased kidney function, swelling due to fluid build-up in your body



Talk to your doctor if you have any liver problems; your doctor may stop treatment if needed. Signs that your liver may not be working properly: nausea, vomiting, fever, pain in your stomach, jaundice, dark coloured urine, itching of your skin, lethargy or fatigue, flu-like syndrome (joint and muscle pain with fever). If you notice any of these signs, tell your doctor immediately



Inform your doctor if you are taking any medications. The use of the following may give you more side effects: angiotensin converting enzyme inhibitors, mineralocorticoid receptor antagonists, potassium supplements, potassium-sparing medicines, salt substitutes and medicines used to treat fungal or bacterial infections.

Do not take sparsentan if you are taking angiotensin blockers, endothelin receptor blockers or renin inhibitors



This medicine can cause side effects such as dizziness, which can affect your ability to drive or use machines. Wait for these effects to pass before driving or using machines again



DO NOT take sparsentan if you are pregnant or planning to become pregnant. This medicine may harm the unborn baby

If you are a woman who can become pregnant, your doctor will ask you to take a pregnancy test before you start treatment

If it is possible that you could become pregnant, use a reliable form of birth control (contraception) while you are taking this medicine and for 1 month after treatment has stopped. Depending on your method of contraception, you may be asked to take regular pregnancy tests during your treatment. Talk to your doctor about this

Stop taking this medicine and talk to your doctor immediately if you become pregnant or think that you maybe pregnant while you are taking, or shortly after stopping, this medicine (up to 1 month)

It is not known if this medicine is transferred into breast milk. Do not breastfeed while you are taking this medicine. Talk to your doctor about this



Do not take this medicine if you are allergic to lactose or any of the ingredients . Please refer to the patient information leaflet for a full list of ingredients.



Your doctor will do blood tests to check your liver function before starting treatment and continue monitoring regularly during treatment

Your patient card, located in this medicine's packaging, contains important safety information about your medication

Please carry this card with you when you leave the house

How to take sparsentan[7]

Always take this medicine exactly as your doctor has told you.
Check with your doctor or pharmacist if you are not sure

How much to take

The recommended starting dose is one 200 mg tablet taken once a day. After 14 days, your doctor will increase the dose to 400 mg (two tablets containing 200 mg or one tablet containing 400 mg) taken once a day by taking into account your tolerability to this medicine



Weeks 1 & 2



Week 3+



Swallow each tablet whole to avoid a bitter taste
It is recommended to take this medicine with a glass of water

It can be taken with or without food, as with other medications, it can be helpful to establish a consistent daily routine when taking this medicine

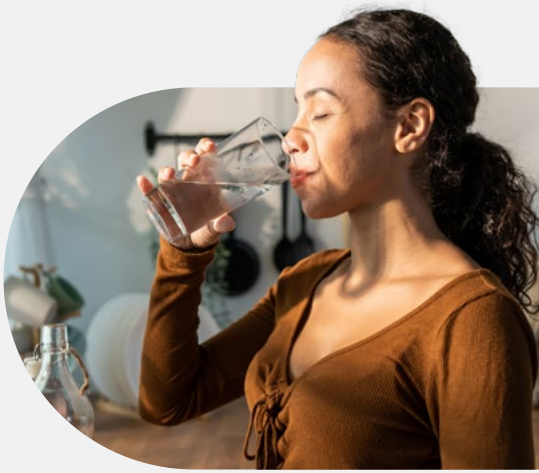
It is important to ensure you are taking your prescribed medication as indicated by your doctor. Treatment should not be stopped without speaking to your doctor, as they may wish to adjust your treatment plan, particularly your blood pressure lowering medication

If you have taken more of this medicine than you have been told to take, you may experience signs and symptoms of low blood pressure (dizziness, lightheadedness, blurred vision and fainting)

If you take too many tablets, contact your doctor immediately

It is very important that you:[7]

- **DO NOT** stop taking this medicine unless your doctor tells you to. Always take this medicine exactly as your doctor has told you
- Avoid grapefruit and grapefruit juice
- Keep this medicine out of reach of children as it is not recommended for children under 18 years
- **Tell your doctor about all other medicines you take. To learn more about medicines you should avoid during treatment with this medicine, you should refer to the patient information leaflet or speak with your doctor**
- Report any adverse events or side effects you experience whilst taking this medicine, such as low blood pressure, dizziness, signs your liver isn't working properly, or swelling. Adverse events reporting information can be found in the following pages of this leaflet
- Continue with any lifestyle modification advice that has been given to you by your doctor, including dietary sodium restrictions, limiting alcohol consumption, weight control and exercise[10]



If you miss a dose

- If you miss a dose of this medicine, skip the missed dose and then take the next dose at your regularly scheduled time
- **DO NOT** take a double dose to make up for a forgotten dose

Please refer to the patient information leaflet for any questions about this medicine or talk to your doctor if there is anything you are unsure of

Possible side effects[7]

Like all medicines, sparsentan can cause side effects, although not everybody gets them. Please inform your doctor or pharmacist if any side effects occur, including side effects not listed in this brochure or in the patient information leaflet:



Very common

(may affect more than 1 in 10 people)

- Low blood pressure (hypotension)

Common

(may affect up to 1 in 10 people)

- Feeling dizzy or lightheaded on standing or sitting up
- Dizziness
- High blood potassium levels (hyperkalaemia)
- Accumulation of fluid in the body (oedema or swelling), especially in the ankles and feet
- Fatigue (tiredness)
- Reduced kidney function (especially when starting treatment; renal impairment)
- Sudden renal failure (especially when starting treatment; acute kidney injury)
- Increased blood levels of creatinine a breakdown product of muscle removed by the kidneys)
- Headache
- Changes in liver function, seen in blood tests



Uncommon

(may affect up to 1 in 100 people)

- Low levels of red blood cells (anaemia)



To learn more about the possible side effects of this medicine, you should read the patient information leaflet or speak to your doctor

Reporting of side effects:

If you experience any side effects, talk to your doctor. This includes any possible side effects not listed here or in the Patient Information Leaflet. You can also report side effects directly via the HPRA website at: http://www.hpra.ie/homepage/about-us/report-an-issue. Adverse events should be reported to Vifor Pharma UK Ltd. Tel: +44 1276 853633. E-mail: MedicalInfo_UK@viforpharma.com. By reporting side effects, you can help provide more information on the safety of this medicine.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information.


Not actual patients

Talk to your doctor if you have any questions about IgAN and your treatment with sparsentan

References

ANG II, angiotensin II; **eGFR,** estimated glomerular filtration rate; **ET-1,** endothelin 1; **g/day,** grams per day; **g/g,** grams per gram; **IgA,** immunoglobulin A; **IgAN,** immunoglobulin A nephropathy; **mg,** milligram

1. McGrogan A, *et al. Nephrol Dial Transplant.* 2011;26:414–30. **2.** Lai KN, *et al. Nat Rev Dis Primers.* 2016;2:16001. **3.** Sharma S, Smyth B. *Kidney Blood Press Res.* 2021;46(4):411–20. **4.** Komers R, Plotkin H. *Am J Physiol Regul Integr Comp Physiol.* 2016;310:R877–84. **5.** Pitcher D, *et al. Clin J Am Soc Nephrol.* 2023;18(6):727–38. **6.** Campbell KN, *et al. Int J Nephrol Renovasc Dis.* 2023;16:281–91. **7.** Sparsentan EU Patient Information Leaflet. **8.** Kidney Disease: Improving Global Outcomes (KDIGO) IgAN and IgAV Work Group. *Kidney Int.* 2025;108(4S):S1–S71. **9.** National Kidney Foundation; Know Your Kidney Numbers: Two Simple Tests. Available at https://www.kidney.org/atoz/content/know-your-kidney-numbers-two-simpletests. Date Accessed: October 2026. **10.** IgA Nephropathy Foundation. IgAN Nutrition. Available at https://igan.org/nutrition/. Date Accessed: October 2026.

The next page is intended for you to take any notes during your appointment with your doctor

Notes