

Product	Filspari	
Country	Great Britain	
Manufacturer	VIT	
SAP Number	3102022-02S	Min. Ver.: 01
Manufacturer Identification Number	n/a	
Fonts	Nimbus (min. 8.6 pt)	
Dimensions	200 × 300 mm	
Colours/Flats		
Black		
Non-Printed Colours		
Keyline/Cutter		

Package leaflet: Information for the patient

Filspari 200 mg film-coated tablets
Filspari 400 mg film-coated tablets
sparsentan

▼ 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 the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- The package also contains a Patient Card. Please read it through as it contains important safety information you need to be aware of before and during your treatment with Filspari.

What is in this leaflet

1. What Filspari is and what it is used for
2. What you need to know before you take Filspari
3. How to take Filspari
4. Possible side effects
5. How to store Filspari
6. Contents of the pack and other information

1. What Filspari is and what it is used for

Filspari contains the active substance sparsentan. Filspari works by blocking the receptors (targets) for two hormones called endothelin and angiotensin which are involved in regulating kidney function.

Filspari is used to treat **primary immunoglobulin A nephropathy (IgAN)** in adults with a urine protein excretion ≥ 1.0 g/day (or urine protein-to-creatinine ratio ≥ 0.75 g/g).

Primary IgAN is a disease caused by the immune system (the body's natural defences) producing a faulty version of an antibody called immunoglobulin A (IgA), which builds up in clusters of small blood vessels in the kidney, called glomeruli, that filter the blood. This build-up damages the glomeruli, causing leakage of blood and protein into the urine.

Filspari blocks the receptors (targets) of two hormones called endothelin and angiotensin that play a role in regulating processes in the kidney such as inflammation that lead to progression of kidney damage. By blocking these receptors, Filspari lowers the amount of protein that leaks into the urine, and thereby helps to slow down progression of the disease.

2. What you need to know before you take Filspari

Do not take Filspari if you are

- allergic to sparsentan or any of the other ingredients of this medicine (listed in section 6)
- pregnant, think you may be pregnant or are planning to become pregnant (see section 2 'Pregnancy and breast-feeding').
- taking any of the following medicines used mainly to treat high blood pressure:
 - angiotensin receptor blockers (such as irbesartan, losartan, valsartan, candesartan, telmisartan),
 - endothelin receptor blockers (such as bosentan, ambrisentan, macitentan, sitaxentan), or
 - renin inhibitors (such as aliskiren)

Warnings and precautions

- Talk to your doctor or pharmacist before taking Filspari if you:
- have low blood pressure (hypotension). Low blood pressure may occur more frequently in elderly patients – your doctor

may check your blood pressure during the treatment and change the dose of Filspari or stop treatment with Filspari if needed.

- have decreased kidney function – your doctor may perform additional tests to monitor how well your kidneys are working (by determining creatinine and potassium levels in your blood)
- get swelling in the hands, ankles, or feet due to fluid build-up in your body – your doctor may ask you to take additional medicine to remove water from your body or your doctor may change the dose of Filspari
- have liver problems – your doctor will do blood tests before you start treatment and at regular intervals during treatment to check whether your liver is working properly; your doctor may stop treatment with Filspari if needed. Signs that your liver may not be working properly: nausea (urge to vomit), vomiting, fever (high temperature), pain in your stomach (abdomen), jaundice (yellowing of your skin or the whites of your eyes), dark-coloured urine, itching of your skin, lethargy or fatigue (unusual tiredness or exhaustion), flu-like syndrome (joint and muscle pain with fever). If you notice any of these signs, **tell your doctor immediately**.

Children and adolescents

Filspari is not recommended for children under 18 years, as it has not been studied in this age group.

Other medicines and Filspari

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking medicines that are used to treat high blood pressure. Do not take Filspari if you are taking any of the following medicines: angiotensin receptor blockers, endothelin receptor blockers, and renin inhibitors (medicines that contain aliskiren) (see section 2 'Do not take Filspari').

Talk to your doctor or pharmacist if you are taking any of the following medicines:

- The concomitant use of Filspari with the following medicines may give more side effects:
- enalapril or lisinopril (or similar medicines, called ACE inhibitors) normally used to treat high blood pressure or for any other reasons. Side effects might be low blood pressure when getting up from a lying or sitting position, high blood potassium levels and reduced kidney function
 - spironolactone or eplerenone (or similar medicines, called MRAs) normally used to remove excess of fluid or to treat heart diseases as may increase level of potassium in your blood
 - potassium supplements, potassium-sparing medicines (such as medicines to remove water from the body or diuretics), or salt substitutes containing potassium as may increase level of potassium in your blood
 - medicines used to treat fungal infections (such as itraconazole, fluconazole).
 - medicines used to treat bacterial infections (such as clarithromycin, erythromycin).

The effect of Filspari may be reduced by medicines such as:

- rifampicin used to treat bacterial infections
- some medicines to treat HIV infections such as efavirenz
- medicines to treat epilepsy such as carbamazepine, phenytoin, phenobarbital
- St. John's Wort (*Hypericum perforatum*) used for depression and other conditions
- corticosteroids such as dexamethasone mainly used to treat inflammation

The effect of Filspari may be increased by medicines such as:

- boceprevir or telaprevir used to treat hepatitis C
- conivaptan used to treat low blood sodium levels
- some medicines to treat HIV infections such as indinavir, lopinavir/ritonavir, nelfinavir, ritonavir
- nefazodone used to treat depression
- medicines to suppress the immune system and prevent transplant rejection such as ciclosporin and tacrolimus

Filspari with food and drink

Grapefruit and grapefruit juice should not be consumed by people who are prescribed Filspari. This is because grapefruit and grapefruit juice can give more side effects in combination with Filspari.

Pregnancy and breastfeeding

Do not take Filspari if you are pregnant or planning to become pregnant. Filspari 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 taking Filspari.

- If it is possible that you could become pregnant, use a reliable form of birth control (contraception) while you are taking Filspari 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 Filspari and talk to your doctor immediately if you become pregnant or think that you may be pregnant while you are taking Filspari, or shortly after stopping Filspari (up to 1 month).

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

Driving and using machines

Filspari may cause side effects, such as dizziness, that may have a minor effect on your ability to drive or use machines (see section 4). Wait for these effects to pass before you drive or use machines.

Filspari contains lactose

If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

Filspari contains sodium

This medicine contains less than 1 mmol sodium (23 mg) sodium per tablet, that is to say essentially “sodium-free”.

3. How to take Filspari

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 (2 tablets containing 200 mg of Filspari or 1 tablet containing 400 mg of Filspari) tablet taken once a day by taking into account your tolerability to Filspari.

Taking this medicine

Swallow the tablet whole to avoid bitter taste. Take with 1 glass of water.

If you take more Filspari than you should

If you have taken more tablets than you have been told to take, you may experience signs and symptoms of low blood pressure. If you take too many tablets, contact your doctor immediately.

If you forget to take Filspari

Skip the missed dose. Then take the next dose at your regularly scheduled time. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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 because of a drop in blood pressure (orthostatic hypotension)
- 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, as measured in blood tests

Uncommon (may affect up to 1 in 100 people):

- low levels of red blood cells (anaemia)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Filspari

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the carton and label after ‘EXP’. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Filspari contains

- The active substance is sparsentan: Each Filspari 200 mg film-coated tablet contains 200 mg of sparsentan. Each Filspari 400 mg film-coated tablet contains 400 mg of sparsentan.
- The other ingredients are: microcrystalline cellulose, lactose (see section 2, ‘Filspari contains lactose’), sodium starch glycolate (type A) (see section 2, ‘Filspari contains sodium’), colloidal anhydrous silica, magnesium stearate, poly(vinyl alcohol), macrogol, talc, titanium dioxide (E171).

What Filspari looks like and contents of the pack

Filspari 200 mg film-coated tablets are white to off-white, oval-shaped film-coated tablets with the number “105” on one side. The dimensions of the tablets are approximately 13 mm × 7 mm.

Filspari 400 mg film-coated tablets are white to off-white, oval-shaped film-coated tablets with the number “021” on one side. The dimensions of the tablets are approximately 18 mm × 8 mm.

Filspari 200 mg and 400 mg film-coated tablets are supplied in a bottle of 30 film-coated tablets.

Marketing authorisation holder and manufacturer

Vifor France
100 – 101 Terrasse Boieldieu
Tour Franklin La Défense 8
92042 Paris La Défense Cedex
France

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