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Filspari (*sparsentan*)

An overview of Filspari and why it is authorised in the EU

What is Filspari and what is it used for?

Filspari is a medicine used to treat adults with primary immunoglobulin A nephropathy, a disease where the kidneys gradually stop working and eventually fail, requiring patients to have dialysis (a process for removing unwanted substances or excess fluid from the blood) or a kidney transplant. Primary means that the cause of the disease is unknown.

The medicine is to be used in people who have at least 1 g of protein in their urine per day or a urine protein-to-creatinine ratio of at least 0.75 g/g (another measure of protein levels in the urine).

Filspari was designated an 'orphan medicine' (a medicine used in rare diseases) on 19 October 2020. Further information on the orphan designation can be found on the EMA website.

Filspari contains the active substance sparsentan.

How is Filspari used?

Filspari can only be obtained with a prescription and is available as tablets to be taken by mouth once a day.

For more information about using Filspari, see the package leaflet or contact your doctor or pharmacist.

How does Filspari work?

The active substance in Filspari, sparsentan, blocks the receptors (targets) for two hormones called endothelin and angiotensin, which are involved in processes that lead to kidney damage. By blocking these receptors, Filspari lowers the level of protein in the urine (proteinuria, a sign of kidney damage), and helps to slow progression of the disease.

What benefits of Filspari have been shown in studies?

Filspari has been found to be effective at reducing proteinuria in people with immunoglobulin A nephropathy in a main study.

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The study involved 404 adults with immunoglobulin A nephropathy and high levels of proteinuria (at least 1 g per day) despite receiving other treatment to slow disease progression. It compared the effect of Filspari on proteinuria with that of irbesartan (a medicine used as part of the standard treatment of immunoglobulin A nephropathy). After 36 weeks of treatment, the level of proteinuria had dropped by an average of 50% in people receiving Filspari compared with an average of 15% in those taking irbesartan. After 2 years, these figures were 43% for people using Filspari, compared with 4% for those using irbesartan.

The study data also indicate that Filspari slows the decline in kidney function, as seen in the change in estimated glomerular filtration rate (eGFR; a measure of how well the kidneys are working). A decrease in eGFR indicates a decline in kidney function. After 2 years of treatment, eGFR had dropped by 2.9 ml/min/1.73m^2/year in people receiving Filspari, compared with 3.9 ml/min/1.73m^2/year in those receiving irbesartan.

What are the risks associated with Filspari?

For the full list of side effects and restrictions with Filspari, see the package leaflet.

The most common side effects with Filspari (which may affect up to 1 in 10 people) include hypotension (low blood pressure), hyperkalaemia (high potassium levels in the blood), dizziness and peripheral oedema (swelling of the arms and legs).

The most common serious side effect, which may affect up to 1 in 100 people, is acute (sudden-onset) kidney injury.

Filspari must not be used during pregnancy. It must also not be used together with angiotensin receptor blockers or endothelin receptor antagonists (other medicines that act on the angiotensin or endothelin receptors) or with medicines called renin inhibitors.

Why is Filspari authorised in the EU?

At the time of approval, there were limited authorised treatments for patients with immunoglobulin A nephropathy. Filspari has been shown to effectively reduce the level of excess protein in the urine and slows the decline in kidney function in adults with this disease. Treatment with Filspari is generally well tolerated, provided that appropriate precautions are taken. The European Medicines Agency therefore decided that the benefits of Filspari are greater than its risks and it can be authorised for use in the EU.

Filspari has been given 'conditional authorisation'. This means that it has been authorised on the basis of less comprehensive data than are normally required because it fulfils an unmet medical need. The Agency considers that the benefit of having the medicine available earlier outweighs any risks associated with using it while awaiting further evidence.

The company has to provide further data on Filspari. It must submit long-term results from the main study on the safety and effectiveness of Filspari in the treatment of adults with primary immunoglobulin A nephropathy. Every year, the European Medicines Agency will review any new information that becomes available.

What measures are being taken to ensure the safe and effective use of Filspari?

The company that markets Filspari will make a patient card available to people using the medicine, which includes information about the risks to the unborn baby if the medicine is used during pregnancy and the risks of liver damage, as well as advice on when to consult a healthcare professional.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Filspari have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Filspari are continuously monitored. Suspected side effects reported with Filspari are carefully evaluated and any necessary action taken to protect patients.

Other information about Filspari

Filspari received a conditional marketing authorisation valid throughout the EU on 19 April 2024.

Further information on Filspari can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/filspari.

This overview was last updated in 04-2024 .