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Vafseo (*vadadustat*)

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

What is Vafseo and what is it used for?

Vafseo is a medicine used to treat the symptoms of anaemia (low red blood cell counts) caused by chronic kidney disease (long-term, progressive decrease in the ability of the kidneys to work properly) in adult patients on dialysis (a technique for removing unwanted substances and excess fluid from the blood when the kidneys do not work well enough).

Vafseo contains the active substance vadadustat.

How is Vafseo used?

Vafseo can only be obtained with a prescription, and treatment should be started by a doctor experienced in the management of anaemia. It is available as tablets to be taken once a day.

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

How does Vafseo work?

Patients with chronic kidney disease may not produce enough erythropoietin, a hormone needed to stimulate the production of red blood cells. The active substance in Vafseo, vadadustat, acts on an enzyme called hypoxia-inducible factor prolyl hydroxylase (HIF-PH). This stimulates the natural response that normally occurs when oxygen levels are low, including the production of erythropoietin and red blood cells.

What benefits of Vafseo have been shown in studies?

Two main studies involving nearly 4,000 patients with anaemia caused by chronic kidney disease who were on dialysis showed that Vafseo was as effective as darbepoetin alfa (another medicine for treating anaemia) at increasing blood levels of haemoglobin.

What are the risks associated with Vafseo?

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

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The most common side effects with Vafseo (which may affect more than 1 in 10 people) include thromboembolic events (problems due to the formation of blood clots in the blood vessels), diarrhoea and hypertension (high blood pressure).

Why is Vafseo authorised in the EU?

Vafseo was shown to be as effective as the comparator medicine darbepoetin alfa at treating anaemia in patients with chronic kidney disease who were on dialysis. With regard to safety, the risk of thromboembolic events in patients treated with Vafseo is addressed with warnings in the prescribing information. The European Medicines Agency therefore decided that Vafseo's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Vafseo

Vafseo received a marketing authorisation valid throughout the EU on 24 April 2023.

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

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