



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/453588/2021
EMA/H/C/004871

Evrenzo (*roxadustat*)

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

What is Evrenzo and what is it used for?

Evrenzo is a medicine used in adults to treat the symptoms of anaemia (low red blood cell counts) caused by chronic kidney failure (long-term, progressive decrease in the ability of the kidneys to work properly).

Evrenzo contains the active substance roxadustat.

How is Evrenzo used?

Evrenzo can only be obtained with a prescription, and treatment should be started by a doctor experienced in the management of anaemia.

Evrenzo is available as tablets to be taken 3 times a week, not on consecutive days.

The starting dose depends on the patient's weight. It is then adjusted in order to achieve and maintain a level of haemoglobin (the protein in red blood cells that carries oxygen around the body) between 10 and 12 g/dL.

Patients treated with an erythropoietin stimulating agent (ESA, a medicine that stimulates production of red blood cells) and whose haemoglobin levels are stable should not be switched to Evrenzo unless there is a clinical justification and expected benefits. For these patients, the starting dose of Evrenzo will depend on the type and dose of ESA used.

Evrenzo should be stopped if haemoglobin levels do not increase within 24 weeks.

For more information about using Evrenzo, see the package leaflet or contact your healthcare provider.

How does Evrenzo work?

Patients with chronic kidney disease may not produce enough of a hormone, erythropoietin, needed to stimulate the production of red blood cells. The active substance in Evrenzo, roxadustat, 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 haemoglobin. This is expected to reduce the symptoms of anaemia.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



What benefits of Evrenzo have been shown in studies?

Evrenzo was investigated in 4 studies in patients with anaemia associated with chronic kidney disease who were not on dialysis (a technique for removing unwanted substances and excess fluid from the blood when the kidneys do not work well enough) and in 4 studies in patients on dialysis.

Three studies with patients who were not on dialysis and not being treated with ESA compared Evrenzo with placebo (a dummy treatment). The results from the 3 studies were consistent and showed overall that around 80% of patients (1,899 out of 2,389) who received Evrenzo achieved the target level of haemoglobin in the first 6 months (11 g/dL and increase from baseline levels by at least 1 g/dL, or by at least 2 g/dL in patients with baseline levels below 8 g/dL) compared with about 9% (163 out of 1,886) of patients given placebo. In the fourth study conducted in patients who were not on dialysis, Evrenzo was compared with an ESA. Results were comparable and showed that Evrenzo and ESA had similar effects on the level of haemoglobin.

In 4 studies carried out in over 4,700 patients on dialysis who were using an ESA, half of the patients were switched to Evrenzo. The results were consistent across the 4 studies and showed that the change in haemoglobin levels from baseline was similar between the groups that switched to Evrenzo and those who stayed on ESA therapy (on average a 0.6 g/dL increase with Evrenzo vs. a 0.3 g/dL increase with ESA). The proportion of patients who achieved the target haemoglobin levels in the first 6 months was also similar between the groups.

What are the risks associated with Evrenzo?

The most common side effects with Evrenzo (which may affect more than 1 in 10 people) are hypertension (high blood pressure), vascular access thrombosis (formation of blood clots in the blood vessels associated with dialysis), diarrhoea, peripheral oedema (swelling especially of the ankles and feet), hyperkalaemia (high blood potassium levels) and nausea (feeling sick).

The most common serious side effects (which may affect up to 1 in 10 people) are sepsis (blood poisoning), hyperkalaemia, hypertension and deep vein thrombosis (blood clot in a deep vein, usually in the leg).

Evrenzo must not be used in people who are allergic to peanuts, soya, or the active substance or any other ingredients of Evrenzo. It must also not be used in women who are breastfeeding or during the third trimester of pregnancy.

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

Why is Evrenzo authorised in the EU?

Evrenzo has been shown to increase and maintain appropriate levels of haemoglobin in patients with anaemia associated with chronic kidney disease, whether they are on dialysis or not. The medicine, which is taken by mouth, was shown to be as effective as ESA, a therapy given by injection. In terms of safety, Evrenzo's side effects are considered manageable and comparable to ESA therapy. The European Medicines Agency therefore decided that Evrenzo'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 Evrenzo?

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

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

Other information about Evrenzo

Evrenzo received a marketing authorisation valid throughout the EU on 18 August 2021.

Further information on Evrenzo can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/evrenzo.

This overview was last updated in August 2021.