EMA/580223/2023
EMEA/H/C/004180

Veltassa (*patiromer*)

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

What is Veltassa and what is it used for?

Veltassa is a medicine used for treating adults and adolescents aged 12 years and above with high levels of potassium in the blood (hyperkalaemia). Hyperkalaemia can cause serious heart problems and muscle weakness.

Veltassa contains the active substance patiromer.

How is Veltassa used?

Veltassa is available as sachets containing a powder for mixing with water, liquid or soft food and is to be taken by mouth once daily. The recommended starting dose depends on the patient's age; the dose is adjusted based on the patient's blood levels of potassium.

The medicine can only be obtained with a prescription. For more information about using Veltassa, see the package leaflet or contact your doctor or pharmacist.

How does Veltassa work?

When Veltassa is taken by mouth, the active substance, patiromer, remains in the gut where it attaches tightly to potassium to form a compound that is then passed out in the stool. In this way, patiromer draws potassium from the body into the gut and so reduces the amount of potassium in the blood.

What benefits of Veltassa have been shown in studies?

One main study involving adults with chronic kidney disease who had hyperkalaemia found that Veltassa is effective in reducing potassium levels in the blood.

In the first part of the study, 243 patients with hyperkalaemia (with an average potassium level of 5.6 mmol/litre) were treated with Veltassa. After 4 weeks of treatment, their potassium level fell on average by 1.0 mmol/litre.

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

The second part of the study compared Veltassa with placebo (a dummy treatment) in 107 patients whose potassium level had fallen with Veltassa during the first part of the study. After 4 weeks, the average potassium level did not change in patients who received Veltassa but it went back up by an average of 0.7 mmol/litre in patients who received placebo.

Another study involved 14 adolescents aged 12 years and above with hyperkalaemia (with an average potassium level of 5.5 mmol/litre). After 14 days of treatment with Veltassa, their potassium levels fell on average by 0.5 mmol/litre. This effect persisted, leading to an average reduction by 1.1 mmol/litre after 26 weeks of treatment.

What are the risks associated with Veltassa?

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

The most common side effects with Veltassa (which may affect up to 1 in 10 people) include constipation, diarrhoea, abdominal (belly) pain, wind and low levels of magnesium in the blood.

Why is Veltassa authorised in the EU?

The European Medicines Agency decided that Veltassa's benefits are greater than its risks and it can be authorised for use in the EU. The Agency considered that there is a need for effective treatment of hyperkalaemia and Veltassa achieves a meaningful lowering of potassium levels. The side effects are relatively moderate but the doctor should take them into account when considering treatment with Veltassa.

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

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

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

Other information about Veltassa

Veltassa received a marketing authorisation valid throughout the EU on 19 July 2017.

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

This summary was last updated in 01-2024.