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EPAR summary for the public

Veltassa

patiromer

This is a summary of the European public assessment report (EPAR) for Veltassa. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Veltassa.

For practical information about using Veltassa, patients should read the package leaflet or contact their doctor or pharmacist.

What is Veltassa and what is it used for?

Veltassa is a medicine used for treating adults 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 (8.4, 16.8 and 25.2 g) of patiromer containing a powder for mixing with water or some fruit juices and taking by mouth. The recommended starting dose is 8.4 g once a day. The doctor then adjusts the dose at intervals of at least one week, based on the patient's blood levels of potassium. The maximum dose is 25.2 g once a day. The Veltassa mixture should be taken with food and at least 3 hours before or after any other medicines the patient takes by mouth. For further information, see the package leaflet.

The medicine can only be obtained with a prescription.

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

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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 patients 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 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.

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

What are the risks associated with Veltassa?

The most common side effects with Veltassa (which may affect more than 1 in 100 people) are those affecting the digestive system (constipation, diarrhoea, abdominal pain and wind) and blood tests showing low levels of magnesium in the blood. For the full list of all side effects and restrictions with Veltassa, see the package leaflet.

Why is Veltassa approved?

The European Medicines Agency decided that Veltassa's benefits are greater than its risks and recommended that it be approved 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.

Other information about Veltassa

The European Commission granted a marketing authorisation valid throughout the European Union for Veltassa on 19 July 2017.

The full EPAR for Veltassa can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Veltassa, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05/2017.