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EPAR summary for the public

Lokelma

sodium zirconium cyclosilicate

This is a summary of the European public assessment report (EPAR) for Lokelma. 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 Lokelma.

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

What is Lokelma and what is it used for?

Lokelma is a medicine used to treat hyperkalaemia (high levels of potassium in the blood) in adults. It contains the active substance sodium zirconium cyclosilicate.

How is Lokelma used?

Lokelma is available as powder sachets (5 g and 10 g). The powder is stirred into water to make a mixture to be drunk straight away. The recommended starting dose of Lokelma is 10 g three times a day. Once the blood levels of potassium return within the normal range (usually within 1–2 days), patients should take the lowest effective dose of Lokelma to prevent the return of hyperkalaemia, starting with 5 g once a day and not exceeding 10 g once a day. For further information, see the package leaflet.

The medicine can only be obtained with a prescription.

How does Lokelma work?

The active substance in Lokelma, sodium zirconium cyclosilicate, is a potassium binder. When taken by mouth, Lokelma attaches to potassium from food and body fluids in the gut, forming a compound that

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is then eliminated in the stools. This action removes potassium from the body overall, thus helping to lower the potassium levels in the blood.

What benefits of Lokelma have been shown in studies?

Lokelma is effective at lowering blood potassium levels and keeping levels of potassium within the normal range.

In a main study of 754 patients with hyperkalaemia, 86% of patients taking Lokelma 10 g had normal potassium levels after 2 days compared with 48% of those taking placebo (a dummy treatment). In addition, when patients who had normal potassium levels after Lokelma treatment were given further treatment with either Lokelma or placebo, potassium levels stayed normal for longer with Lokelma than with placebo.

Another main study involved 258 patients who had normal potassium levels after Lokelma treatment. In this 4-week study, patients receiving further treatment with Lokelma had lower potassium levels from the second week of treatment than patients taking placebo.

What are the risks associated with Lokelma?

The most common side effects with Lokelma (which may affect up to 1 in 10 people) are oedema (fluid build-up with swelling in the ankles and feet) and hypokalaemia (low levels of potassium in the blood).

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

Why is Lokelma approved?

The European Medicines Agency decided that Lokelma's benefits are greater than its risks and recommended that it be approved for use in the EU. The Agency considered that Lokelma is effective at controlling blood potassium levels, especially during initial (acute) treatment. The overall safety profile is considered acceptable.

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

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

Other information about Lokelma

The European Commission granted a marketing authorisation valid throughout the European Union for Lokelma on 22 March 2018.

The full EPAR for Lokelma 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 Lokelma, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2018.