

Public Summary SwissPAR dated 2 July 2021

Lokelma[®] (active substance: sodium zirconium cyclo-silicate)

First authorisation in Switzerland: 16 April 2021

Medicinal product for the treatment of hyperkalaemia (high potassium levels) in adults

About the medicinal product

The medicinal product Lokelma contains the active substance sodium zirconium cyclosilicate.

Lokelma is used for the treatment of hyperkalaemia in adults. Hyperkalaemia means that the level of potassium in the blood is too high.

Lokelma lowers the level of potassium in the body and ensures that it remains within the normal range. Lokelma works by binding potassium when it passes through the stomach

and bowel after ingestion. Both are then excreted with the stool, thereby reducing the amount of potassium in the body.

Lokelma is added as a powder to still water and drunk.

Lokelma is available on prescription only. The doctor checks the potassium level in the blood and determines the correct dosage accordingly.

Information on authorisation

In deciding whether to authorise the medicinal product Lokelma, Swissmedic took into account the assessments of the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and the corresponding product information.

Since the assessment of the clinical data was based on the assessment reports of the foreign partner authorities, the preconditions

for a SwissPAR (Swiss Public Assessment Report) and a resulting Public Summary SwissPAR are not fully met. Swissmedic refers to the authorisation of the foreign comparator products.

www.ema.europa.eu

www.fda.gov

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Lokelma, the Information for healthcare professionals and the Patient information (package leaflet) were not yet available. As soon as the medicine becomes available in Switzerland, the Information for

healthcare professionals and the Patient information will be made available on the following website: www.swissmedicinfo.ch

Healthcare professionals (doctors, pharmacists and others) can answer any questions about this medicine.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.