10 November 2022
EMA/18088/2023
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): sodium zirconium cyclosilicate

Procedure No. EMEA/H/C/PSUSA/00010675/202203

Period covered by the PSUR: 22/03/2021 To: 21/03/2022

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for sodium zirconium cyclosilicate, the scientific conclusions of CHMP are as follows:

In view of available case reports including cases with gastrointestinal perforations, the PRAC agrees with the MAH's proposal to correct information that intestinal perforations have been reported with potassium binders including Lokelma.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for sodium zirconium cyclosilicate the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing sodium zirconium cyclosilicate is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.