EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): linaclotide

Procedure No. EMEA/H/C/PSUSA/00010025/201908

Period covered by the PSUR: 28/08/2018 To: 28/08/2019

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Scientific conclusions

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

In view of available data on the signal of "urticaria" from clinical trials and spontaneous reports including in 17 cases with a close temporal relationship and a positive de-challenge as well as two cases with a positive re-challenge the PRAC considers a causal relationship between linaclotide and urticaria is established. The PRAC concluded that the product information of products containing linaclotide should be amended accordingly.

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 linaclotide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing linaclotide 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.