



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 April 2026
EMADOC-1700519818-3273509
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. PSUSA/00010025/202508

Period covered by the PSUR: 1 year to 29 August 2025



Scientific conclusions

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

In view of available data on anaphylactic reaction from spontaneous reports including cases with a close temporal relationship, typical symptoms, typical treatment and a positive de-challenge, the PRAC considers a causal relationship between linaclotide and anaphylactic reaction is at least a reasonable possibility. The PRAC concluded that the product information of products containing linaclotide should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

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.

Update of section 4.8 of the SmPC to add anaphylactic reaction with a frequency not known. The Package leaflet is updated accordingly.

Summary of Product Characteristics

Section 4.8

The following adverse reaction(s) should be added under the SOC Immune system disorders with a frequency of “not known”:

Anaphylactic reaction

Package Leaflet

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects:

Stop using < product name > and seek medical attention immediately if you experience any of the following symptoms: difficulty breathing, light-headedness, fainting, fast heartbeat, swelling of the face, throat, or other parts of the body and sweating. These could be signs of an anaphylactic reaction (sudden, severe allergic reaction) (not known: frequency cannot be estimated from the available data).