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): teduglutide

Procedure No. EMEA/H/C/PSUSA/00009305/201908

Period covered by the PSUR: 29/08/2018 To: 29/08/2019

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Scientific conclusions

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

Based on cumulative data on renal disorders from registry TED-R13-002, literature, post-marketing and clinical studies chronic renal disorders are an underlying complication of patients with short bowel syndrome (SBS) receiving parenteral nutrition. Whilst not directly related to the treatment with teduglutide, also acute and renal failure (ARF) which is a serious condition occurs frequently in the post-marketing setting. ARF appears to be due to dehydration and other metabolic stressors such as infection, intestinal obstruction and during the postoperative period. In general, dehydration can be prevented by appropriate and timely monitoring for fluid and electrolyte imbalance, and subsequent adjustment of parenteral fluid and electrolytes. Considering the seriousness of ARF and its preventability, the warning on the risks of dehydration and fluid imbalances was strengthened and the package leaflet was updated 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 teduglutide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing teduglutide 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.