13 October 2022
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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): lonapegsomatropin

Procedure No. EMEA/H/C/PSUSA/00010969/202202

Period covered by the PSUR: 25/08/2021 to 25/02/2022

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Scientific conclusions

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

In view of available data on serious hypersensitivity reactions from clinical trials and spontaneous reports including two cases with a close temporal relationship, adverse events unlikely to be attributed to disease or other treatments, clinically reasonable response to withdrawal and symptom-related acute therapy, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between lonapegsomatropin and anaphylactic reactions including angioedema is at least a reasonable possibility. The PRAC concluded that the product information of medicinal products containing lonapegsomatropin should be amended accordingly.

Update of sections 4.4 and 4.8 of the SmPC to include a warning on anaphylactic reactions including angioedema and add anaphylactic reactions (including angioedema) as an adverse drug reaction with a frequency 'uncommon'. The Package leaflet is 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 lonapegsomatropin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing lonapegsomatropin 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.