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): lonapegsomatropin

Procedure No. EMEA/H/C/PSUSA/00010969/202402

Period covered by the PSUR:
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Scientific conclusions

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

In view of available data on the risk of osteonecrosis in association with growth hormone treatment from the literature and spontaneous reporting, the PRAC considers osteonecrosis a potential risk of lonapegsomatropin treatment, also taking into account the fact that the risk of osteonecrosis (sometimes as Legg-Calve-Perthes disease) has already been reflected in the product information for some other medicinal products containing growth hormone. The PRAC Rapporteur concluded that the product information of medicinal products containing lonapegsomatropin 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 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.