27 June 2024
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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): pasireotide

Procedure No. EMEA/H/C/PSUSA/00009253/202310

Period covered by the PSUR: 24 October 2020 to 24 October 2023

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

In view of available data on the risk for steatorrhea/discoloured faeces from spontaneous reports including in 17 cases with a close temporal relationship and 4 cases with a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between pasireotide, and steatorrhea/discoloured faeces is at least a reasonable possibility. The PRAC concluded that the product information of products containing pasireotide 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 pasireotide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pasireotide 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.