22 July 2021
EMA/567225/2021
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): edotreotide

Procedure No. EMEA/H/C/PSUSA/00010552/202012

Period covered by the PSUR: 7 December 2019 – 7 December 2020

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 edotreotide, the scientific conclusions of CHMP are as follows:

In view of available data on the impact of splenosis and accessory intrapancreatic spleen on PET findings interpretation errors from the literature, and in view of a plausible mechanism of action, the PRAC concluded that the product information of products containing edotreotide should be amended 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 edotreotide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing edotreotide 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.