



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 January 2021
EMA/30770/2021
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): mitotane

Procedure No. EMEA/H/C/PSUSA/00002075/202004

Period covered by the PSUR: 27 April 2017 to 27 April 2020



Scientific conclusions

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

In view of available data on risk(s) from clinical trial(s), the literature, spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a causal relationship between mitotane and hypogonadism is at least a reasonable possibility. The PRAC concluded that the product information of products containing mitotane 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 mitotane the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing mitotane 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.