21 March 2024
EMA/107562/2024
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): leuprorelin (depot formulations)

Procedure No. EMEA/H/C/PSUSA/00010877/202307

Period covered by the PSUR: 24/05/2022 To: 31/07/2023

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Scientific conclusions

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

In view of available data on fatty liver from the literature and non-clinical data and on Severe cutaneous adverse reactions (SCARs) from the literature and post marketing cases, the PRAC considers a causal relationship between leuprorelin and fatty liver and SCARs is at least a reasonable possibility. The PRAC concluded that the product information of products containing leuprorelin 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 leuprorelin (depot formulations) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing leuprorelin (depot formulations) 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.