16 December 2021
EMA/28536/2022
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): ulipristal (female emergency contraceptive)

Procedure No. EMEA/H/C/PSUSA/00003074/202105

Period covered by the PSUR: 15/05/2020 to 14/05/2021

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Scientific conclusions

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

In view of available data on spontaneous reports including in some cases a close temporal relationship, and in view of ulipristal acetate 5 mg with indication uterine fibroids having drug hypersensitivity listed with frequency uncommon, the PRAC considers a causal relationship between ulipristal acetate 30 mg at least a reasonable possibility. The PRAC concluded that the product information of products containing ulipristal acetate 30 mg with indication emergency contraceptives 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 ulipristal (female emergency contraceptive) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ulipristal (female emergency contraceptive) 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.