



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 October 2017
EMA/11208/2018
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 acetate (treatment of moderate to severe symptoms of uterine fibroids)

Procedure No. EMEA/H/C/PSUSA/00009325/201702

Period covered by the PSUR: 23 February 2016 to 22 February 2017



Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for ulipristal acetate (treatment of moderate to severe symptoms of uterine fibroids), the scientific conclusions of CHMP are as follows:

A cumulative review of hypersensitivity based on pooled data from the phase III clinical trials (PEARL studies and VENUS I) identified 43 non-serious adverse events, 7 of which (pruritus, generalised oedema, hypersensitivity with swelling face in one patient, rash generalised and urticarial) were considered related to ulipristal acetate. In the post-marketing setting, 132 cases of hypersensitivity reactions have been reported cumulatively. Taking into account the cases of positive re- and de-challenge and the close temporal association, causality between drug hypersensitivity and ulipristal acetate can be concluded with an at least reasonable possibility.

With regards to angioedema, 3 serious cases of angioedema have been reported in the post-marketing setting. Considering the close temporal association and positive de-challenge a causal association between ulipristal acetate and angioedema is at least of reasonable possibility.

Therefore, in view of available data, changes to section 4.8 of the SmPC are considered warranted, to add the adverse reactions of drug hypersensitivity with a frequency uncommon and of angioedema with a frequency not known. The Package leaflet is updated 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 acetate (treatment of moderate to severe symptoms of uterine fibroids) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ulipristal acetate (treatment of moderate to severe symptoms of uterine fibroids) 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.