21 March 2013
EMA/721048/2013
Committee for Medicinal Products for Human Use (CHMP)

Zoely

International non-proprietary name: nomegestrol / estradiol

Procedure No. EMEA/H/C/001213/PSU/005

Period covered by the PSUR: 27 January 2012 to 26 July 2012

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Zoely, the scientific conclusions of PRAC are as follows:

During the reporting period of the PSUR, 7 cases of venous thromboembolic events have been reported in post-marketing (5 cases were serious) with a favourable relationship with nomegestrol/estradiol. The role of nomegestrol/estradiol in the occurrence of these 7 cases is considered as “possible” by the PRAC. It has to be highlighted that all women who experienced VTE under nomegestrol/estradiol presented risk factor of thromboembolic event, especially in a relatively advanced age. In order to know if this consideration is a consequence of a preferential prescription of this new Combined Oral Contraceptive containing 17β-estradiol to women of advanced age, the MAH is requested to provide in the next PSUR a distribution of the exposed patients by age.

Venous Thromboembolic Events are already considered as a therapeutic class effect with Combined Oral Contraceptive and appear in the SmPC of nomegestrol/estradiol under section 4.4. VTE are unlisted under section 4.8. Based on this review of the safety data, VTE cases with nomegestrol/estradiol have now been reported. The MAH is requested to amend the section 4.8 of the SmPC and the package leaflet of nomegestrol/estradiol.

Moreover, three cases of hypersensitivity reactions with nomegestrol/estradiol have been reported during the reporting period of the PSUR. The PRAC considers the responsibility of nomegestrol/estradiol as possible in the occurrence of these cases. Therefore, the MAH is asked to amend section 4.8 of the SmPC and to continue to closely monitor this issue.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Zoely, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance nomegestrol/estradiol is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.