EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/CHMP/612251/2014
Committee for Medicinal Products for Human Use (CHMP)

Fareston

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: toremifene

Procedure No.: EMEA/H/C/PSUSA/00002999/201309

Period covered by the PSUR: 1 October 2010 to 30 September 2013

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Scientific conclusions

Based on the review of the cumulative data and literature review submitted in this PSUR procedure, the PRAC considers it necessary to update the Product Information of Fareston and include events of thrombocytopenia, anaemia and leukopenia in section 4.8 of the SmPC ('Undesirable effects') with frequency 'unknown'.

In addition, in section 4.4 'Precaution for use', the statement that anaemia, leukopenia and thrombocytopenia have been reported; red blood cell, leukocyte or platelet counts should be monitored when using FARESTON is to be added. The PL is to be modified accordingly.

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 TOREMIFENE the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance TOREMIFENE is favourable subject to the proposed changes to the product information

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