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Committee for Medicinal Products for Human Use (CHMP)

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/00002999/201409

Period covered by the PSUR: 1 October 2013 to 30 September 2014

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Scientific conclusions

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

The chronological, clinical and biological data strongly suggested that toremifene can increase transaminase levels and also potentially induce severe acute liver injury with a predominant hepatocellular pattern of biological abnormalities, occurring within 3 months of treatment in 90% of cases with known treatment duration. Potentially severe liver injury was observed in 39.5% of patients of whom two developed fulminant hepatic failure.

In addition, with regards to the risk of drug interactions, no particular signal suggestive of drug interaction with toremifene as a substrate or an enzyme inhibitor emerged from the data submitted by the MAH. However, in order to provide clear information to the prescriber, the PRAC recommended that the product information should be amended to list relevant examples of drugs known to inhibit the CYP 3A enzyme system and to delete troleandomycin which is not further marketed.

Therefore, in view of available data regarding toremifene, the PRAC considered that changes to the product information were warranted.

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(s) containing TOREMIFENE is favourable subject to the proposed changes to the product information

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