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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): paclitaxel albumin

Procedure No. EMEA/H/C/PSUSA/00010123/201601

Period covered by the PSUR: 7 January 2015 – 6 January 2016

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for paclitaxel albumin, the scientific conclusions of CHMP are as follows:

Drug interaction regarding CYP2C8:

Paclitaxel is metabolised by CYP2C8 and CYP3A4. Inhibition of these enzymes may lead to increased exposure of paclitaxel and hence increased toxicity of paclitaxel. It was only recently that the strong, time-dependent CYP2C8-inhibiting effects of clopidogrel's metabolite clopidogrel acyl-β-D-glucuronide, in humans were found. During the current PSUR review period. The first description of the clinical relevance of the interaction between paclitaxel and clopidogrel has been published by Bergmann et al. (Br J Clin Pharmacol. 2016), and in addition, this interaction has also been described in an article by Shinoda et al., Biomed Tep 2016.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing paclitaxel albumin were warranted.

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 paclitaxel albumin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing paclitaxel albumin 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.