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Committee for Medicinal Products for Human Use (CHMP)

Savene

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

International non-proprietary name: dexrazoxane

Procedure no.: EMEA/H/C/PSUSA/00001001/201402

Period covered by the PSUR: 28 July 2010 – 28 February 2014

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Scientific conclusions

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

There is no evidence from the available data to suggest a differential level of risk between dexrazoxane containing medicinal products authorised for different indications with regards to the main identified risks for these products. It is therefore considered necessary for dexrazoxane indicated for the treatment of anthracycline extravasation in adults to adequately reflect the risks of anaphylactic reaction and hypersensitivity as well as to update the instructions for the safe handling of these products.

For dexrazoxane indicated for prevention of chronic cumulative cardiotoxicity caused by doxorubicin or epirubicin use the risk of liver disorders and the risks associated with the concomitant use of dexrazoxane and yellow fever vaccine, live attenuated vaccines, ciclosporin, tacrolimus, phenytoin and myelosuppressive medicines should be reflected in the product information respectively.

Therefore, in view of available data regarding the risk of anaphylactic reaction and hypersensitivity, the risk of liver disorders, the risks of systemic disease following the use of live vaccines, concomitant use with ciclosporin, tacrolimus, phenytoin and myelosuppressive medicines, and the safe handling of dexrazoxane 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 DEXRAZOXANE the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing DEXRAZOXANE 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.