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Committee for Medicinal Products for Human Use (CHMP)

Myocet

Doxorubicin

Procedure No: EMEA/H/C/000297/PSU/019

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

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Scientific conclusions

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

Safety of liposomal doxorubicin is well-established. Palmar-plantar erythrodysthesias (PPE) is a known adverse reaction for conventional Doxorubicin and pegylated liposomal doxorubicin. PPE was closely monitored for non-pegylated liposomal doxorubicin. Cumulatively 18 cases have been reported from post-marketing experience and 8 cases from clinical trials. Among these cases, 4 have been reported where a causal relationship could be regarded as at least possible and an update of the Product Information is therefore warranted.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Myocet the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance doxorubicin is favourable subject to the proposed changes to the product information.

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