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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: eribulin

Procedure No. EMEA/H/C/PSUSA/00001254/201411

Period covered by the PSUR: 15 November 2013 - 14 November 2014

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Scientific conclusions

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

During eribulin administration via infusion, a substantial part of the solution may be lost as result of normal gravity flow. The PRAC was of the opinion that an additional warning on the need for flushing the intravenous line was necessary to ensure administration of the complete dose. Thus, an update of section 6.6 of the SmPC and section 3 of the package leaflet was recommended.

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