EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Pixuvri

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

International non-proprietary name: pixantrone dimaleate

Procedure No. EMEA/H/C/002055/PSUV/0015

Period covered by the PSUR: 11 May 2013 – 10 November 2013

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Scientific conclusions

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

Based on the PRAC review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing the active substance pixantrone remains favourable but recommends that the terms of the marketing authorisation should be varied as based on the data from the PSUR, updates to section 4.4 and 4.8 of the SmPC with respect to secondary malignancies (specifically AML and MDS) are required. The package leaflet is updated accordingly. 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 Pixuvri, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance pixantrone dimaleate 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.