EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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:BEXAROTENE

Procedure No. EMEA/H/C/PSUSA/00000404/201409

Period covered by the PSUR: 16 September 2011 to 15 September 2014

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

Following the review of a case of severe hypoglycemia after exposure in combination with a sulfonylurea (gliclazide) the PRAC considered further strengthening the current information on interactions between bexarotene and insulin, agents enhancing insulin secretion or insulin-sensitisers. Information about this interaction is currently mentioned in section 4.4 of the SmPC, but should also be mentioned in section 4.5 of the SmPC in line with the Guideline on Summary of Product Characteristics.

Therefore, in view of available data regarding interactions between bexarotene and insulin, agents enhancing insulin secretion or insulin-sensitisers, 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 bexarotene the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing bexarotene is favourable subject to the proposed changes to the product information

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