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Committee for Medicinal Products for Human Use (CHMP)

Nevanac

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

International non-proprietary name: nepafenac

Procedure No. EMEA/H/C/000818/PSUV/0029

Period covered by the PSUR: 01 December 2013 – 30 May 2014

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Scientific conclusions

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

Following reports of one case of “corneal perforation” within this PSUR, a search of EudraVigilance was performed which revealed two medically confirmed ICSRs during the reporting interval, and two medically confirmed ICSRs and one non-medically confirmed ICSR cumulatively and outside the reporting period.
Due to the cumulative number of ICSRs with a plausible temporal association with nepafenac, the severity of the reaction, which is a sight-threatening condition, and considering that corneal perforation is already included in section 4.8 of the SmPC of similar topical NSAIDs from the same pharmacological class, the PRAC recommends to include corneal perforation in section 4.8 of the SmPC for nepafenac. For the purpose of clarity, the PRAC also recommended to cross-reference this information to the appropriate wording in section 4.4 of the SmPC. The Patient Leaflet is updated accordingly.

Therefore, in view of available data regarding corneal perforation, 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 Nevanac, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance nepafenac is favourable subject to the proposed changes to the product information.

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