EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 2016
EMA/CHMP/421658/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Nevanac

nepafenac

On 23 June 2016 last day of the CHMP meeting, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Nevanac. The marketing authorisation holder for this medicinal product is Alcon Laboratories (UK) Ltd.

Nevanac is available as eye drops in two different strengths, 1 mg/ml and 3 mg/ml. The CHMP adopted a new indication for the 3 mg/ml strength as follows:

"Reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients."

For information, the full indications for Nevanac 3mg/ml will be as follows:

"Nevanac 3 mg/ml is indicated in adults for:[2]

- Prevention and treatment of postoperative pain and inflammation associated with cataract surgery
- **Reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients (see section 5.1)**"

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold

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