17 March 2017
EMA/CVMP/140608/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Novem

International non-proprietary name (INN): meloxicam

On 16 March 2017, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of an extension to the terms of the marketing authorisation for the veterinary medicinal product Novem. The marketing authorisation holder for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

Novem is currently authorised as solution for injection for cattle and pigs. The extension concerns the addition of a new strength 40 mg/ml solution for injection for cattle for subcutaneous use, for the following indications: "For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs, for use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle, for adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy and for the relief of post-operative pain following dehorning in calves".

Detailed conditions for the use of this product are described in the updated summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the extension to the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Novem and therefore recommends the granting of the extension to the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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