9 December 2016
EMA/CVMP/741734/2016
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (extension)

EQUIOXX

International non-proprietary name (INN): firocoxib

On 8 December 2016, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product EQUIOXX 57 mg, chewable tablets, intended for alleviation of pain and inflammation associated with osteoarthritis and reduction of associated lameness in horses. The applicant for this veterinary medicinal product is MERIAL.

EQUIOXX is an anti-inflammatory and antirheumatic nonsteroidal medicinal product containing firocoxib (ATCvet code QM01AH90) as active substance. Firocoxib is a non-steroidal anti-inflammatory drug (NSAID) belonging to the coxibs group, which acts by selective inhibition of cyclooxygenase-2 (COX-2) – mediated prostaglandin synthesis.

The benefits of EQUIOXX 57 mg, chewable tablets are its efficacy for the alleviation of pain and inflammation associated with osteoarthritis and reduction of associated lameness in horses of 450-600 kg bodyweight. The most common side effects are lesions (erosion/ulceration) of the oral mucosa and of the skin around the mouth. These lesions are mild and resolve without treatment.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) and will be available in all official European Union languages after 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 EQUIOXX 57 mg, chewable tablets and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.
[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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