European Medicines Agency
Veterinary Medicines and Inspections

London, 16 May 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*
EQUIOXX

International Non-proprietary Name (INN):
Firocoxib

On 14 May 2008, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending granting a marketing authorisation for the veterinary medicinal product EQUIOXX 8.2 mg/g oral paste, intended for the alleviation of pain and inflammation associated with osteoarthritis and reduction of associated lameness in horses. EQUIOXX oral paste for horses is presented in pre-filled oral syringes. The Applicant for this veterinary medicinal product is Merial S.A.S.

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

EQUIOXX 0.82% oral paste for horses is presented in pre-filled oral syringes containing 7.32 g of oral paste labelled in 100-kg dosing increments. Each syringe contains sufficient product to treat a 600 kg horse. The intended therapeutic dose in horses is 0.1 mg firocoxib/kg bw/day orally for up to 14 consecutive days. The most common side effects are lesions (erosion/ulceration) of the oral mucosa and of the skin around the mouth. Typically, these lesions are mild and resolve without treatment.

The proposed withdrawal period for meat and offal (horse) is 26 days. No withdrawal period has been established for milk and EQUIOXX should therefore not be used in mares producing milk for human consumption.

The approved indication is: “Alleviation of pain and inflammation associated with osteoarthritis and reduction of associated lameness in horses”.

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 to risk balance for EQUIOXX and therefore recommends the granting of the marketing authorisation.

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* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

** Applicants may appeal any CVMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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