European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*
TROCOXIL

International Non-proprietary Name (INN):
Mavacoxib

On 16 July 2008, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending the granting of a marketing authorisation for the veterinary medicinal product Trocoxil, chewable tablets for dogs, intended for treatment of pain and inflammation associated with degenerative joint disease in dogs in cases where continuous treatment exceeding one month is indicated. The Applicant for this veterinary medicinal product is Pfizer Ltd, United Kingdom.

The active substance of Trocoxil is mavacoxib, a non-steroidal anti-inflammatory drug (NSAID) of the coxib class (ATCvet Code QM01AH92). The principal mode of action is inhibition of cyclooxygenase (COX).

The benefits of Trocoxil are its relief of pain and inflammation in dogs with degenerative joint disease. This is a MONTHLY treatment where the initial dose is given in accordance with the posology on the SPC, repeated 14 days later and then monthly dosed for up to a maximum of 7 consecutive doses (6.5 months). The most common side effects are loss of appetite, diarrhea and vomiting which have occasionally been reported.

The approved indication is: “For the treatment of pain and inflammation associated with degenerative joint disease in dogs in cases where continuous treatment exceeding one month is indicated”.

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 Trocoxil and therefore recommends the granting of the marketing authorisation.

* 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.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.europa.eu http://www.emea.europa.eu