



European Medicines Agency
Veterinary Medicines and Inspections

London, 19 September 2008
Doc. Ref.: EMEA/CVMP/461247/2008

**COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
POST-AUTHORISATION SUMMARY OF OPINION*
PREVICOX**

International Non-proprietary Name (INN):
Firocoxib

On 17 September 2008, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a variation to the terms of the marketing authorisation for the veterinary medicinal product Previcox. The Marketing Authorisation Holder for this veterinary medicinal product is Merial S.A.S.

The change agreed by the CVMP concerns an additional indication to include relief of post-operative pain and inflammation associated with orthopaedic surgery in dogs. Additional warnings are also included in sections 4.5 and 4.6 of the product information based on pharmacovigilance reports received. The approved indication is 'For the relief of pain and inflammation associated with osteoarthritis in dogs. For the relief of post-operative pain and inflammation associated with soft-tissue and orthopaedic surgery in dogs.'

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation/extension to the marketing authorisation has been granted by the European Commission.

* Summaries of opinion are published without prejudice to the Commission Decision.

** 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.