



European Medicines Agency
Veterinary Medicines and Inspections

London, 17 October 2008
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**COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
POST-AUTHORISATION SUMMARY OF OPINION***

FLEXICAM

International Non-proprietary Name (INN):
MELOXICAM

On 15 October 2008, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant an extension to the terms of the marketing authorisation for the veterinary medicinal product Flexicam. The Marketing Authorisation Holder for this veterinary medicinal product is Omnipharm Ltd..

The change agreed by the CVMP concerns a new pharmaceutical form, 5 mg/ml solution for injection.

The approved indication in dogs for Flexicam 5 mg/ml solution for injection is alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders and the reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery. In cats the product is indicated for the reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

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.