European Medicines Agency
Veterinary Medicines and Inspections

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

International Non-proprietary Name (INN):
Meloxicam

On 12 November 2008, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the veterinary medicinal product Loxicom, 0.5 mg/ml and 1.5 mg/ml oral suspension for dogs and 5 mg/ml solution for injection for dogs and cats. The Applicant for this veterinary medicinal product is Norbrook Laboratories Limited. Loxicom is a generic veterinary medicinal product as defined in Article 13(2)(b) of Directive 2001/82/EC, as amended by Directive 2004/28/EC. The reference veterinary medicinal product is Metacam 1.5 mg/ml oral suspension for dogs.

The active substance of Loxicom is meloxicam, a non-steroidal, anti-inflammatory drug (NSAID). Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. In vitro and in vivo studies demonstrated that meloxicam inhibits cyclooxygenase-2(COX-2) to a greater extent than cyclooxygenase-1 (COX-1).
The Pharmacotherapeutic group (ATC Vet code) is QM01AC06.

The benefits of Loxicom are the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs (oral suspension and solution for injection) and in the case of the solution for injection reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery in dogs, and reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery in cats. The most common side effects are loss of appetite, vomiting, diarrhoea, faecal occult blood and apathy have occasionally been reported. These side effects occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal. In the case of the solution for injection in very rare cases anaphylactoid reactions may occur and should be treated symptomatically.

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 Loxicom 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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