15 July 2011
EMA/CVMP/63405/2011
Committee for Medicinal Products for Veterinary Use

Post authorisation summary of opinion*

Loxicom

International non-proprietary name (INN): Meloxicam

On 14 July 2011, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending the extension of the marketing authorisation for the veterinary medicinal product Loxicom. The applicant for this veterinary medicinal product is Norbrook Laboratories Limited.

The active substance of Loxicom is meloxicam, an anti-inflammatory and antirheumatic product, non-steroids (oxicams) ATC vet code: QM01AC06.

Loxicom is currently authorised as oral suspensions for dogs and cats, as solutions for injection for dogs and cats and as a solution for injection for cattle, pigs and horses. The new extension concerns chewable tablets for dogs. The new presentations will be available as 1 mg and 2.5 mg chewable tablets and are to be administered orally.

Typical adverse reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure 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.

The approved indication is the "alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs".

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 1 mg and 2.5 mg chewable tablets for dogs, and therefore recommends the granting of the extension 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 European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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