6 May 2011
EMA/CVMP/62249/2011
Committee for Medicinal Products for Veterinary Use

Post authorisation summary of opinion*

Loxicom

International non-proprietary name (INN): Meloxicam

On 5 May 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 marketing authorisation holder 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 an oral suspension and solution for injection for dogs and cats. The new extension concerns a solution for injection for cattle, pigs and horses.

The new presentations will be available as a new 20 mg/ml solution for injection and are to be administered by subcutaneous or intravenous use in cattle, intramuscular use in pigs and intravenous use in horses.

The most common side effects are a slight transient swelling at the injection site.

The approved indication is:

Cattle: For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle. For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle. For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.

Pigs: For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation. For adjunctive therapy in the treatment of puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy.

* 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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Horses: For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders. For the relief of pain associated with equine colic.

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 20 mg/ml solution for injection for cattle, pigs and horses and therefore recommends the granting of the extension of the marketing authorisation

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