8 February 2013
EMA/CVMP/33458/2013
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Meloxidolor

International non-proprietary name (INN): Meloxicam

On 7 February 2013, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Meloxidolor, a meloxicam 5 mg/ml solution for injection for use in dogs, cats, cattle and pigs, 20 mg/ml solution for injection for use in cattle, pigs and horses and 40 mg/ml solution for injection for use in cattle and horses. The applicant for this veterinary medicinal product is Le Vet Beheer B.V.

The active substance of Meloxidolor is meloxicam, an anti-inflammatory and anti-rheumatic product, non-steroids (oxicams) ATCvet code: QM01AC06.

The benefits of Meloxidolor are the alleviation of inflammation and relief of pain in the approved indications. In dogs and cats, occasional side effects of Meloxidolor are those seen with NSAIDs, such as loss of appetite, vomiting, diarrhoea, blood appearing in the stools and lethargy (lack of vitality). In dogs, these side effects occur usually within the first week of treatment and are generally transient (temporary). They disappear once treatment has stopped. In very rare cases, they may be serious or fatal.

The most common side effects are a slight transient swelling at the injection site following subcutaneous administration in cattle and in horses a transient swelling at the injection site.

The approved indications are:

Dogs: Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery.

Cats: Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[2] 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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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 the relief of post-operative pain associated with minor soft tissue surgery such as castration. For adjunctive therapy in the treatment of puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy.

Horses: For use in the alleviation of inflammation and relief of pain in both acute and chronic musculoskeletal 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 Meloxidolor and therefore recommends the granting of the marketing authorisation.