

15 June 2012  
EMA/CVMP/310571/2012  
Committee for Medicinal Products for Veterinary Use

## **Post authorisation summary of opinion\***

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### **Inflacam - Extension**

International non-proprietary name (INN): Meloxicam

On 12-14 June 2012, 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 Inflacam. The applicant for this veterinary medicinal product is Chanelle Pharmaceuticals Manufacturing Limited.

Inflacam is currently authorised as 1.5 mg/ml oral suspension for dogs, 1 mg and 2.5 mg chewable tablets for dogs, 15 mg/ml oral suspension for horses and 20 mg/ml solution for injection for cattle, pigs and horses. The new extension concerns a 5 mg/ml solution for injection for use in dogs and cats.

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

The new presentations will be available as 10 ml, 20 ml and 100 ml pack sizes and are to be administered in dogs by subcutaneous or intravenous use and in cats by subcutaneous use.

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 very rare cases anaphylactoid reactions may occur and should be treated symptomatically.

The approved indications are in dogs the 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 it will be used in 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 summary of product characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will

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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 European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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 Inlacam 5 mg/ml solution for injection for dogs and cats, and therefore recommends the granting of the extension of the marketing authorisation.