14 October 2011
EMA/CVMP/778856/2011
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

Inflacam

Meloxicam

On 13 October 2011, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion, [2]recommending to grant a marketing authorisation for the veterinary medicinal product Inflacam, 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, intended for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. The applicant for this veterinary medicinal product is Chanelle Pharmaceuticals Manufacturing Limited.

Inflacam 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 Inflacam is meloxicam, a non-steroidal, anti-inflammatory drug (NSAID). Meloxicam is an 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 Inflacam are the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. 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 cattle, pigs and horses a transient swelling at the injection site can occur.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
[2] 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

The approved indications are:

1.5 mg/ml, oral suspension for dogs.1 mg and 2.5 mg chewable tablets for dogs and 15 mg/ml oral suspension for horses

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders.

20 mg/ml solution for injection for cattle, horses and pigs

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.

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 Inflacam and therefore recommends the granting of the marketing authorisation.