14 September 2018
EMA/CVMP/543202/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Inflacam

International non-proprietary name (INN): meloxicam

On 13 September 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of an extension to the terms of the marketing authorisation for the veterinary medicinal product Inflacam. The marketing authorisation holder for this veterinary medicinal product is Chanelle Pharmaceuticals Manufacturing Ltd.

Inflacam is currently available in different pharmaceutical forms and strengths, including oral suspension for dogs (1.5 mg/ml) and horses (15 mg/ml), chewable tablets for dogs (1 mg and 2.5 mg), solution for injection for dogs, cats, cattle and pigs (5 mg/ml), solution for injection for cattle, pigs and horses (20 mg/ml), and granules for horses (330 mg).

The active substance in Inflacam is meloxicam, a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class (ATCvet code: QM01AC06).

This extension application is to add an oral suspension of 0.5 mg meloxicam/ml for the existing target species cats. The route of administration is oral use. The new presentation is a multi-dose product and will be available in pack sizes containing bottles of 10 ml or 15 ml with a syringe.

The benefit of Inflacam 0.5 mg/ml oral suspension is to allow oral treatment of cats for the alleviation of mild to moderate post-operative pain and inflammation following surgical procedures, e.g. orthopaedic and soft tissue surgery, and for the alleviation of pain and inflammation in acute and chronic musculo-skeletal disorders. Dide effects typical for non-steroidal anti-inflammatory drugs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, lethargy and renal failure have occasionally been reported. These side effects are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

Detailed conditions for the use of this product are described in the updated summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the extension to the marketing authorisation has been granted by the European Commission.

[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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Inflacam 0.5 mg/ml oral suspension for cats and therefore recommends the granting of the extension to the marketing authorisation of Inflacam.