9 October 2015
EMA/CVMP/596354/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Inflacam

International non-proprietary name (INN): meloxicam

On 8 October 2015, 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 Limited.

Inflacam is currently authorised as an 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), and solution for injection for cattle, pigs and horses (20 mg/ml).

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

The new extension application is to add a new pharmaceutical form (granules in sachet) and a new strength (330 mg) for the existing target species horses. The route of administration is oral for in-feed use. The new presentation is a single-dose product and will be available in pack sizes containing 100 sachets.

The benefits of Inflacam 330 mg granules for horses are its efficacy in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders in horses weighing between 500 and 600 kg.

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.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Inflacam 330 mg granules for horses and therefore recommends the granting of the extension of the marketing authorisation.

[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 5555
Send a question via our website www.ema.europa.eu/contact