EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 December 2011
EMA/CVMP/77474/2011
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

RevitaCAM 5 mg/ml oromucosal spray for dogs

Meloxicam

On 8 December 2011, 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 RevitaCAM 5 mg/ml oromucosal spray for dogs intended for alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. The applicant for this veterinary medicinal product is Abbott Laboratories Ltd.

The active substance of RevitaCAM 5 mg/ml oromucosal spray for dogs 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 RevitaCAM 5 mg/ml oromucosal spray for dogs are the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders and an alternative means of product administration in the form of a pump spray. The most common side effects are loss of appetite, vomiting, diarrhoea, faecal occult blood and apathy which 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.

The approved indication is: 'alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders'.

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

[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 European Medicines Agency 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

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 RevitaCAM 5 mg/ml oromucosal spray for dogs and therefore recommends the granting of the marketing authorisation.