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EPAR summary for the public

RevitaCAM

meloxicam

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use.

This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the scientific discussion (also part of the EPAR).

What is RevitaCAM?

RevitaCAM is a medicine that contains the active substance meloxicam. It is available as a 5 mg/ml oromucosal spray (a spray administered to the back of the mouth, towards the gums and /or inner cheek) for dogs. It is available in pumps of different sizes (6 ml, 11 ml and 33 ml) delivering appropriate amounts of meloxicam for dogs of different weights.

RevitaCAM is similar to Metacam oral solution containing the same active substance, but given in a different way, as an oromucosal spray.

What is RevitaCAM used for?

RevitaCAM is used in dogs to relieve inflammation and pain. It can be used for chronic (long term) musculo-skeletal disorders and for acute (sudden and short-lived) disorders, for instance, due to injury.

The pump size and the number of sprays to be given are determined by the dog's weight. Treatment should be started at a single dose of 0.2 mg/kg body weight on the first day, and then continued at a maintenance dose of 0.1 mg/kg body weight once a day. The spray should be administered into the dog's mouth, with the mist being directed to the back and towards the gums and/or inner cheek.

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A response is normally seen within three to four days. Treatment should be discontinued after 10 days if no improvement is seen. For longer term treatment, the dose can be decreased to the lowest effective dose once a response has been seen.

How does RevitaCAM work?

RevitaCAM contains meloxicam, which belongs to a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Meloxicam acts by blocking an enzyme called cyclo-oxygenase which is involved in the production of prostaglandins. As prostaglandins trigger inflammation, pain, exudation and fever, meloxicam reduces these signs and symptoms.

How has RevitaCAM been studied?

Studies provided for RevitaCAM were tests to determine that it is bioequivalent to the reference medicine, Metacam. Various studies looked at how RevitaCAM was absorbed and its effects in the body, in comparison with Metacam.

What benefit has RevitaCAM shown during the studies?

Based on the findings of the study, RevitaCAM was considered to be bioequivalent to the reference medicine. Consequently, RevitaCAM's benefit is taken as being the same as that of the reference medicine.

What is the risk associated with RevitaCAM?

Side effects sometimes seen with other NSAIDs, such as loss of appetite, vomiting, diarrhoea, blood appearing in the stools, renal (kidney) failure and apathy (lack of vitality) are occasionally seen with RevitaCAM. These generally occur within the first week of treatment and usually disappear once treatment has stopped. In very rare cases they may be serious or fatal.

In some dogs sneezing, coughing, gagging or drooling may be seen immediately after treatment administration.

RevitaCAM must not be used in dogs with liver, heart or kidney problems, bleeding disorders, or dogs suffering from irritation or ulcers of the digestive tract. It must not be used in dogs that are hypersensitive (allergic) to the active substance or to any of the other ingredients. RevitaCAM should not be used in pregnant or lactating animals. RevitaCAM must not be used in dogs less than six weeks of age and should not be used in cats.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

People who are hypersensitive to NSAIDs should avoid contact with RevitaCAM. If accidental exposure occurs, hands should be washed immediately with soap and water. Hands should always be washed after administrating the medicine.

Why has RevitaCAM been approved?

The CVMP considered that, in accordance with European Union requirements, RevitaCAM has been shown to be bioequivalent to Metacam. Therefore the CVMP's view was that, as for Metacam, RevitaCAM's benefits are greater than its risks when used for the approved indications and the

Committee recommended that RevitaCAM be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

Other information about RevitaCAM:

The European Commission granted a marketing authorisation valid throughout the European Union, for RevitaCAM on 23/02/2012. Information on the prescription status of this product may be found on the label of the carton.

This summary was last updated on 18/09/2015.