

EMA/535843/2007 EMEA/V/C/000121

Rheumocam (meloxicam)

An overview of Rheumocam and why it is authorised in the EU

What is Rheumocam and what is it used for?

Rheumocam is an anti-inflammatory medicine used in cattle, pigs, horses, dogs and cats.

Rheumocam contains the active substance meloxicam and is a generic medicine. This means that Rheumocam contains the same active substance and works in the same way as a 'reference medicine' already authorised in the European Union (EU) called Metacam.

Cattle

In cattle, Rheumocam is used together with appropriate antibiotic therapy, to reduce clinical signs of acute respiratory infection (infection of the lungs and airways). It can be used with oral re-hydration therapy (medicines given by mouth to restore water levels in the body) to reduce diarrhoea in calves of over one week of age and young, non-lactating cattle. It can be used as supportive therapy in the treatment of acute mastitis (inflammation of the udder), in combination with antibiotics.

<u>Pigs</u>

In pigs, Rheumocam is used to reduce lameness and inflammation in non-infectious locomotor disorders (diseases that affect the ability to move), for the relief of post-operative pain after minor soft tissue surgery such as castration, and for supportive therapy together with appropriate antibiotic therapy in the treatment of diseases that occur after farrowing (giving birth) such as puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome). Septicaemia and toxaemia are conditions where bacteria circulate in the blood and produce harmful substances (toxins).

Horses

In horses, Rheumocam is used to reduce pain associated with colic (abdominal pain) and to lessen inflammation and relieve pain in acute and chronic musculo-skeletal disorders (disorders affecting the muscles and bones).

Dogs

In dogs, Rheumocam is used to reduce post-operative pain and inflammation following orthopaedic (e.g. fracture operation) and soft tissue surgery. Moreover, it is used to lessen inflammation and pain in acute and chronic musculo-skeletal disorders.



Cats

In cats, Rheumocam is used to reduce post-operative pain and inflammation after ovariohysterectomy (spaying operation), orthopaedic and minor soft tissue surgery. Moreover, it is used to lessen pain and inflammation in acute and chronic musculo-skeletal disorders.

How is Rheumocam used?

Rheumocam is available as granules, an oral (taken by mouth) suspension, chewable tablets and a solution for injection. Injections may be into a vein, muscle or under the skin. The formulation to use depends on the animal and the condition being treated.

Rheumocam can only be obtained with a prescription. For further information about using Rheumocam, see the package leaflet or contact your veterinarian or pharmacist.

How does Rheumocam work?

Rheumocam 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 are substances that trigger inflammation, pain, exudation (fluid that leaks out of blood vessels during an inflammation) and fever, meloxicam reduces these signs of disease.

How has Rheumocam been studied?

Since Rheumocam is a generic medicine, studies have been conducted to determine that it is bioequivalent to the reference medicine, Metacam. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Rheumocam?

Because Rheumocam is a generic and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

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

Safety information has been included in the summary of product characteristics and the package leaflet for Rheumocam, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers. The precautions are the same as for the reference medicine since Rheumocam is a generic medicine.

What is the withdrawal period?

The withdrawal period is the time required after administration of the medicine before an animal can be slaughtered and the meat used for human consumption. It is also the time required after administration of the medicine before milk may be used for human consumption.

Cattle

The withdrawal period for meat is 15 days and for milk it is five days.

Pigs

The withdrawal period for meat is five days.

Horses

The withdrawal period for meat is five days for the 20 mg/ml solution for injection and three days for the granules in sachet and 15 mg/ml oral suspension. The medicine is not authorised for use in horses producing milk for human consumption.

Why is Rheumocam authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Rheumocam has been shown to have comparable quality and to be bioequivalent to Metacam. Therefore the Agency's view was that, as for Metacam, the benefits of Rheumocam, outweigh the identified risks and it can be authorised for use in the EU.

Other information about Rheumocam

Rheumocam received a marketing authorisation valid throughout the EU on 10 January 2008.

Further information on Rheumocam can be found on the Agency's website: ema.europa.eu/Find medicines/European public assessment reports.

Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in September 2018.