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Emdocam (*meloxicam*)

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

What is Emdocam and what is it used for?

Emdocam is an anti-inflammatory medicine used in cattle, pigs, horses, dogs and cats. It contains the active substance meloxicam.

In cattle, Emdocam is used together with antibiotics to reduce clinical signs such as fever and inflammation in acute (short-term) respiratory infection (infection of the lungs and airways). It can be used in diarrhoea in combination with oral rehydration therapy (medicines given by mouth to restore water levels in the body) to reduce clinical signs of the disease in calves of over one week of age and young, non-lactating cattle. It can be used to relieve post-operative pain following dehorning in calves and as supportive therapy in the treatment of acute mastitis (inflammation of the udder), in combination with antibiotics.

In pigs, Emdocam is used to reduce lameness and inflammation in non-infectious locomotor disorders (diseases that affect the ability to move), to relieve postoperative pain associated with minor soft tissue surgery such as castration, and for supportive therapy together with antibiotics in the treatment of diseases that occur after farrowing (giving birth) such as puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome, a bacterial infection of the udder and/or the womb).

In horses, Emdocam is used to relieve pain associated with colic (abdominal pain) and to alleviate inflammation and pain in both acute and chronic (long-term) musculoskeletal disorders (disorders affecting the muscles and bones).

In dogs, Emdocam is used to reduce postoperative pain and inflammation following orthopaedic (e.g. fracture operation) and soft tissue surgery. It is also used to alleviate inflammation and pain in both acute and chronic musculoskeletal disorders in dogs.

In cats, Emdocam is used to reduce postoperative pain and inflammation after ovariohysterectomy (spay operation), orthopaedic and minor soft tissue surgery. It is also used to alleviate pain and inflammation in acute and chronic musculoskeletal disorders.

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

For more information, see the package leaflet.

How is Emdocam used?

Emdocam can only be obtained with a prescription. The medicine is available as an oral suspension (a liquid taken by mouth) and a solution for injection. Injections may be into a vein, muscle or under the skin. The formulation and dose to use depends on the animal species, its bodyweight and the condition being treated.

For more information about using Emdocam, see the package leaflet or contact your veterinarian or pharmacist.

How does Emdocam work?

Emdocam 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 (fluid that leaks out of blood vessels during inflammation) and fever, meloxicam reduces these clinical signs.

How has Emdocam been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Metacam, and do not need to be repeated for Emdocam.

As for every medicine, the company provided studies on the quality of Emdocam. The company also carried out studies for the oral suspension that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

There was no need for 'bioequivalence' studies to investigate whether Emdocam solution for injection is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because when Emdocam is given by injection into a vein, the active substance is delivered straight into the bloodstream. When Emdocam is given by injection under the skin or into the muscle, the active substance is also expected to be absorbed in the same way as that in the reference medicine, because the two medicines have the same composition.

What are the benefits and risks of Emdocam?

Because Emdocam is a generic medicine 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 Emdocam, 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 Emdocam is a generic medicine.

What is the withdrawal period in food-producing animals?

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

Cattle

The withdrawal period is 15 days for meat and 5 days for milk.

Pigs

The withdrawal period for meat is 5 days.

Horses

The meat withdrawal period is 5 days for the solution for injection and 3 days for the oral suspension. The product is not authorised for use in horses producing milk for human consumption.

Why is Emdocam authorised in the EU?

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

Other information about Emdocam

Emdocam received a marketing authorisation valid throughout the EU on 18 August 2011.

Further information on Emdocam can be found on the Agency's website: ema.europa.eu/medicines/veterinary/EPAR/emdocam.

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

This overview was last updated in 08-2021.