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# Inflacam (meloxicam)

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

#### What is Inflacam and what is it used for?

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

Inflacam contains the active substance meloxicam and is a generic medicine. This means that Inflacam 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, Inflacam 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 also be used as supportive therapy in the treatment of acute mastitis (inflammation of the udder), in combination with antibiotics.

#### <u>Pigs</u>

In pigs, Inflacam 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).

#### <u>Horses</u>

In horses, Inflacam 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, Inflacam 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, Inflacam 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 inflammation and pain in acute and chronic musculo-skeletal disorders in cats.

#### How is Inflacam used?

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

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

#### How does Inflacam work?

Inflacam 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 Inflacam been studied?

Since Inflacam 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 Inflacam?

Because Inflacam 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 Inflacam, 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 Inflacam 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 the 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 and 15 mg/ml oral suspension. The medicine is not authorised for use in horses producing milk for human consumption.

## Why is Inflacam authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Inflacam 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 Inflacam outweigh the identified risks and it can be authorised for use in the EU.

# Other information about Inflacam

Inflacam received a marketing authorisation valid throughout the EU on 9 December 2011.

Further information on Inflacam can be found on the Agency's website: <a href="mailto:ema.europa.eu/Find">ema.europa.eu/Find</a> <a href="mailto:medicine/Veterinary Medicines/European public assessment reports">medicine/Veterinary Medicines/European public assessment reports</a>

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

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