



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Loxicom (*meloxicam*)

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

What is Loxicom and what is it used for?

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

Cattle

In cattle, Loxicom 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 (fluids 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 to relieve pain following dehorning in calves and to support the treatment of acute mastitis (inflammation of the udder), in combination with antibiotics.

Pigs

In pigs, Loxicom is used to reduce lameness and inflammation in non-infectious locomotor disorders (diseases that affect the ability to move that are not caused by an infection) and to support together with appropriate antibiotic therapy the treatment of diseases that occur after farrowing (giving birth) such as puerperal septicaemia and toxæmia (mastitis-metritis-agalactia syndrome). Septicaemia and toxæmia are conditions where bacteria circulate in the blood and produce harmful substances (toxins).

Horses

In horses, Loxicom 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, Loxicom is used to reduce pain and inflammation following orthopaedic (e.g. fracture operation) and soft tissue surgery. Moreover, it is used to lessen inflammation and pain in musculo-skeletal disorders.



Cats

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

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

How is Loxicom used?

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

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

How does Loxicom work?

Loxicom 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 an inflammation) and fever, meloxicam reduces these signs of disease.

How has Loxicom 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 Loxicom.

As for every medicine, the company provided studies on the quality of Loxicom. The company also carried out studies 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.

What are the benefits and risks of Loxicom?

Because Loxicom 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 Loxicom, 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 Loxicom 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 five days for milk.

Pigs

For meat the withdrawal period is five days.

Horses

For the 20 mg/ml solution for injection the meat withdrawal period is five days, and for the 50 mg/ml oral paste it is three days. The medicine is not authorised for use in horses producing milk for human consumption.

Why is Loxicom authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Loxicom 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 Loxicom outweighs the identified risk and it can be authorised for use in the EU.

Other information about Loxicom

Loxicom received a marketing authorisation valid throughout the EU on 10 February 2009.

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

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

This overview was last updated in November 2018.