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EPAR summary for the public

Loxicom

meloxicam

This document is a summary of the European Public Assessment Report (EPAR). 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 Loxicom?

Loxicom is a medicine that contains the active substance meloxicam. It is available as oral suspensions (0.5 mg/ml and 1.5 mg/ml), as oral paste (50 mg/g), as chewable tablets (1 mg and 2.5 mg) and solutions for injection (5 mg/ml, and 20 mg/ml).

Loxicom is a 'generic' which means that Loxicom is similar to a 'reference veterinary medicine' already authorised in the EU (Metacam).

What is Loxicom used for?

Loxicom oral suspensions are used to relieve inflammation and pain in cats and dogs. They can be used for chronic (long term) musculo-skeletal disorders, and in dogs it can also be used for acute (sudden and short lived) musculo-skeletal disorders, for instance, due to injury.

Loxicom oral paste (50 mg/g) is used to relieve inflammation and pain in both acute and chronic musculo-skeletal disorders in horses.

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Loxicom chewable tablets can be used in dogs to relieve inflammation and pain in chronic musculo-skeletal disorders as well as in acute disorders.

Loxicom solution for injection (5 mg/ml) can be used to relieve inflammation and pain in dogs following surgery involving the bones or soft tissue and in cats following ovariohysterectomy (spaying) and minor soft tissue surgery.

Loxicom solution for injection (20 mg/ml) is used in cattle, together with appropriate antibiotic therapy, to reduce clinical signs in acute respiratory infections (infection of the lungs and airways) and to treat acute mastitis (inflammation of the udder). It can be used in combination with oral re-hydration therapy (medicines given by mouth to restore water levels in the body) for diarrhoea in calves of over one week of age and in young, non-lactating cattle.

Loxicom solution for injection (20 mg/ml) is used in pigs to reduce the symptoms of lameness and inflammation in non-infectious locomotor disorders (diseases that affect the ability to move) and for the treatment of diseases that occur after farrowing (giving birth) such as puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome), together with appropriate antibiotic therapy. Septicaemia and toxaemia are conditions where bacteria circulate in the blood and produce harmful substances.

Loxicom solution for injection (20 mg/ml) is used in horses to relieve colic (abdominal pain) and the inflammation and pain in acute and chronic musculo-skeletal disorders.

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?

Since Loxicom 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 benefit has Loxicom shown during the studies?

Based on the findings of the studies, Loxicom was considered to be bioequivalent to the reference medicinal product. Consequently, Loxicom's benefit is taken as being the same as that of the reference medicinal product.

What is the risk associated with Loxicom?

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 Loxicom in dogs and cats. 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 horses given the oral paste, isolated cases of slight urticarial (itchy rash) and diarrhoea were observed in clinical trials which were reversible. Commonly, a reduction in the concentration of the blood protein albumin will occur during treatment.

A slight temporary swelling at the injection site following injection under the skin was observed in cattle. In horses, a temporary swelling at the injection site can occur but resolves without intervention.

In very rare cases, potentially serious or fatal anaphylactoid reactions (similar to severe allergic reactions) may occur following administration of the solution for injection and should be treated symptomatically.

Loxicom must not be used in animals with liver, heart or kidney problems, bleeding disorders, or suffering from irritation or ulcers of the gut. It must not be used in animals which are hypersensitive (allergic) to the active substance or to any of the other ingredients.

Loxicom must not be used in pregnant or lactating horses, cats and dogs, but it can be used during pregnancy and lactation for cattle and pigs.

Loxicom must not be used in dogs or horses less than six weeks of age or in cattle less than one week of age when used for the treatment of diarrhoea. It must not be used in cats weighing less than 2 kg.

What is the withdrawal period?

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

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

People who are hypersensitive (allergic) to NSAIDs should avoid contact with Loxicom. If someone swallows or accidentally injects themselves with the medicine, the advice of a doctor should be sought immediately.

Why has Loxicom been approved?

The CVMP considered that, in accordance with European Union requirements, Loxicom has been shown to be bioequivalent to Metacam. Therefore the CVMP's view was that, as for Metacam,

Loxicom's benefits are greater than its risks when used for the approved indications. The Committee recommended that Loxicom be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Loxicom:

The European Commission granted a marketing authorisation valid throughout the European Union, for Loxicom on 10/02/2009. Information on the prescription status of this product may be found on the label of the carton.

This summary was last updated in January 2013.