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EPAR summary for the public

Melovem

Meloxicam

This document is a summary of the European Public Assessment Report. 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 Melovem?

Melovem is a medicine that contains the active substance meloxicam. It is available as a solution for injection (5 mg/ml, 20 mg/ml and 30 mg/ml).

Melovem is a 'generic'. This means that Melovem is similar to a 'reference veterinary medicine' containing the same active substance. While the reference medicine, Metacam, is available as 5 mg/ml and 20 mg/ml solutions for injection, Melovem is also available as a 30 mg/ml solution for injection.

What is Melovem used for?

Melovem is used in cattle, together with appropriate antibiotic therapy, to reduce the signs of acute respiratory infections (infection of the lung and airways). It can be used in combination with oral rehydration therapy (medicines given by mouth to restore water levels in the body) for diarrhoea in calves of over one week of age and young, non-lactating cattle. The 20 mg/ml and 30 mg/ml solutions for injection are also used in combination with antibiotic therapy to treat acute mastitis (inflammation of the udder).

Melovem solution for injection (5 mg/ml, 20 mg/ml and 30 mg/ml) is used in pigs to reduce the symptoms of lameness (inability to walk normally) and inflammation in non-infectious locomotor disorders (diseases that affect the ability to move). The 5 mg/ml solution for injection can be used for the relief of post-operative pain associated with minor soft tissue surgery such as castration (surgical removal of the testicles). The 20 mg/ml and 30 mg/ml solution for injection can be used together with

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appropriate antibiotic therapy for the treatment of diseases that occur after farrowing (giving birth) such as puerperal septicaemia (bacteria present in blood) and toxaemia (a toxic state) (mastitis-metritis-agalactia syndrome).

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

How does Melovem work?

Melovem 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 Melovem been studied?

Studies have been carried out, both in calves and in pigs, to show that Melovem is bioequivalent to the reference medicine, Metacam.

What benefit has Melovem shown during the studies?

As Melovem is considered to be bioequivalent to the reference medicine, its benefit is taken as being the same as that of the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What is the risk associated with Melovem?

A slight temporary swelling at the injection site following injection under the skin and in the muscle was observed in cattle and pigs. 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 injection and should be treated symptomatically.

Melovem must not be used in animals with liver, heart or kidney problems, bleeding disorders, or suffering from irritation or ulcers of the digestive tract. It must not be used in animals which are hypersensitive (allergic) to the active substance or any of the other ingredients. If used for the treatment of diarrhoea in cattle, Melovem must not be used in animals of less than one week of age. Melovem must also not be used in horses less than 6 weeks of age.

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 Melovem. If someone accidentally injects themselves with the medicine, the advice of a doctor should be sought immediately.

What is the withdrawal period?

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

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

Pigs

For meat the withdrawal period is five days.

Horses

For meat the withdrawal period is five days. The product is not authorised for use in horses producing milk for human consumption.

Why has Melovem been approved?

The CVMP decided that, in accordance with European Union requirements, Melovem has been shown to be bioequivalent to Metacam. Therefore, the CVMP's view was that, as for Metacam, Melovem's benefits are greater than its risks for the approved indications and the Committee recommended that Melovem be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Melovem:

The European Commission granted a marketing authorisation valid throughout the European Union, for Melovem on 7 July 2009. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in July 2013.