EMA/534789/2010
EMEA/V/C/002247

EPAR summary for the public

Recocam

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 Recocam?

Recocam is a medicine for cattle, pigs and horses that contains the active substance meloxicam. It is available as a clear yellow solution for injection (20 mg/ml).

Recocam is a 'generic' medicine which means that Recocam is similar to a 'reference veterinary medicine' already authorised in the EU (Metacam). Recocam is 'bioequivalent' to the reference medicine which means that it is equivalent to Metacam in the way it is absorbed and used by the body.

What is Recocam used for?

In cattle it is used together with appropriate antibiotics, to reduce clinical signs of acute respiratory infection (infection of the lungs and airways) and to treat acute mastitis (inflammation of the udder). It can be used with oral re-hydration therapy for diarrhoea in calves of over one week of age and in young, non-lactating cattle. Recocam is given in cattle as a single injection of 0.5 mg per kg body weight under the skin or into a vein.

It 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 certain diseases that occur after farrowing (giving birth) such as puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome), together with appropriate antibiotic therapy. It is given as a single injection of 0.4 mg per kg body weight into a muscle. A second dose may be given after 24 hours if required.

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Recocam is used in horses to relieve colic (abdominal pain) and for the alleviation of inflammation and relief of pain in musculo-skeletal disorders. Recocam is given as a single injection of 0.6 mg per kg body weight into the horse's vein.

How does Recocam work?

Recocam 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 the prostaglandins trigger inflammation, pain, exudation and fever, meloxicam reduces these clinical signs.

How has Recocam been studied?

Although Recocam is a generic medicine no bioequivalence studies have been provided as the composition of the product is sufficiently similar to the reference product Metacam for the products to be considered essentially similar.

What benefit has Recocam shown during the studies?

Recocam was considered to be bioequivalent with the reference medicine. Consequently, Recocam's benefit is taken as being the same as that of the reference medicine.

What is the risk associated with Recocam?

In cattle and pigs, subcutaneous, intramuscular and intravenous administration is well tolerated; only a slight transient swelling at the injection site following subcutaneous administration was observed in less than 10% of cattle treated in clinical studies.

In horses, a transient swelling at the injection site can occur but resolves without intervention. In very rare cases anaphylactoid reactions may occur and should be treated symptomatically.

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 Recocam.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the doctor.

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. The withdrawal period for Recocam for meat is 15 days for cattle and five days for pigs and horses. Milk can be taken five days after administration in cattle. The medicine should not be used in horses producing milk for human consumption.

Why has Recocam been approved?

The CVMP considered that, in accordance with European Union requirements, Recoocam is bioequivalent to Metacam. Therefore the CVMP's view was that, as for Metacam, Recocam's benefits

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

Other information about Recocam:

The European Commission granted a marketing authorisation valid throughout the European Union, for Recocam on 13/09/2011. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on: 02-2013.