European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

MELOXIDYL

EPAR summary for the public

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 Meloxidyl?

Meloxidyl is a medicinal product that contains the active substance meloxicam. Meloxidyl is a pale green oral suspension (1.5 mg/ml) for dogs and (0.5 mg/ml) for cats, which is mixed into the food, and a yellow solution for injection (5 mg/ml) for dogs and cats as well as solution for injection (20 mg/ml) for cattle, pigs and horses.

Meloxidyl is a 'generic': this means that Meloxidyl is similar to a 'reference veterinary medicinal product' already authorised in the EU (Metacam). Studies have been carried out to prove that Meloxidyl is 'bioequivalent' to the reference veterinary medicinal product: this means that Meloxidyl is equivalent to Metacam in the way it is absorbed and used by the body.

What is Meloxidyl used for?

In dogs, Meloxidyl is used as an oral suspension to relieve inflammation and pain in musculo-skeletal disorders. It can be used for both acute (sudden) disorders, such as those seen after an injury, and chronic (long-term) disorders. As an injection, Meloxidyl is also used to reduce the pain and inflammation after an operation, such as orthopaedic or soft tissue surgery.

In cats, Meloxidyl is used as an oral suspension to relieve inflammation and pain in chronic musculo-skeletal disorders as well as to relieve mild to moderate pain after an operation, such as spaying or soft tissue surgery. Meloxidyl injection is used in cats to reduce the pain after an operation, such as spaying or minor soft tissue surgery.

In cattle Meloxidyl injection is used to reduce clinical signs in case of acute respiratory infection with appropriate antibiotic therapy, to reduce clinical signs in case of diarrhoea in combination with oral re-hydration therapy in calves over one week of age and young, non-lactating cattle and as supportive therapy in the treatment of acute mastitis, in combination with antibiotics.

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In pigs Meloxidyl injection is used to reduce the symptoms of lameness and inflammation in non-infectious locomotor disorders and for supportive therapy in the treatment of puerperal septicaemia and toxaemia around farrowing (mastitis-metritis-agalactia syndrome) with appropriate antibiotics.

In horses Meloxidyl injection is used to relieve inflammation and pain in both acute and chronic musculo-skeletal disorders and for the relief of pain associated with colic.

How does Meloxidyl work?

Meloxidyl contains meloxicam, which belongs to a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Meloxicam acts by inhibition of prostaglandin synthesis. As the prostaglandins are substances that trigger inflammation, pain, exudation and fever, meloxicam reduces those responses.

How has Meloxidyl been studied?

A study looked at how Meloxidyl was absorbed and its effects in the body, in comparison with Metacam.

What benefit has Meloxidyl shown during the studies?

Based on the findings of the study, Meloxidyl was considered to be bioequivalent to the reference medicinal product. Because of this, Meloxidyl's benefit is taken as being the same as that of the reference medicinal product.

What is the risk associated with Meloxidyl?

In dogs and cats the side effects seen with Meloxidyl are similar to those seen with other NSAIDs and occur only occasionally. They include loss of appetite, vomiting, diarrhoea, blood in the stools and apathy (lack of vitality). They usually occur during the first week of treatment and tend to be temporary. They disappear once treatment has stopped. In very rare cases, they may be serious or fatal.

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

In horses, anaphlylactoid (hypersensitivity) reactions can occur and should be treated symptomatically. A temporary swelling at the injection site can occur but resolves without intervention.

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

People who are hypersensitive to NSAIDs should avoid contact with Meloxidyl. If someone swallows the medicinal product, the advice of a doctor should be sought immediately. Accidental self-injection may cause pain. If this happens, seek medical advice immediately and show the package leaflet or the label to the doctor.

What is the time to allow before the animal can be slaughtered and the meat used for human consumption (withdrawal period)?

After the last administration of Meloxidyl cattle should not be slaughtered for 15 days and the milk not used for 5 days. Pigs and horses should not be slaughtered for 5 days.

Why has Meloxidyl been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that, in accordance with EU requirements, Meloxidyl has been shown to be bioequivalent to Metacam. Therefore the CVMP's view was that, as for Metacam, Meloxidyl's benefits are greater than its risks. The Committee recommended that Meloxidyl should be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

Other information about Meloxidyl:

The European Commission granted a marketing authorisation valid throughout the European Union for Meloxidyl to Ceva Santé Animal on 15 January 2007. Information on the prescription status of this product may be found on the label of the carton.

This summary was last updated in July 2010.