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EPAR summary for the public

Acticam

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 Acticam?

Acticam contains meloxicam which belongs to a class of medicines having anti-inflammatory action. Acticam is presented as an oral suspension 1.5 mg/ml for dogs (to be given mixed with food) and a solution for injection 5mg/ml.

Acticam is a 'generic': this means that Acticam is similar to a 'reference veterinary medicine' already authorised in the EU (Metacam 1.5 mg/ml oral suspension). Studies have been carried out to prove that Acticam is 'bioequivalent' to the reference veterinary medicine: this means that Acticam is equivalent to Metacam 1.5 mg/ml suspension in the way it is absorbed and used by the body.

What is Acticam used for?

Dogs: Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders and reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery.

Cats: Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

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How does Acticam work?

Acticam 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 Acticam been studied?

Acticam has been investigated in comparison with Metacam which is already authorised in the EU. A study looked at how Acticam was absorbed and its effects in the body, in comparison with Metacam oral suspension 1.5mg/ml.

What benefit has Acticam shown during the studies?

Acticam is efficacious in alleviating the inflammation and pain in both acute and chronic musculo-skeletal disorders and reducing the post operative pain following orthopaedic and soft tissue surgery in dogs and in reducing the post-operative pain after ovariohysterectomy and minor soft tissue surgery in cats.

What is the risk associated with Acticam?

Occasional side effects of Acticam are those seen with NSAIDs, such as loss of appetite, vomiting, diarrhoea, blood appearing in the stools and apathy (lack of vitality). These side effects occur usually within the first week of treatment and are generally temporary. They disappear once treatment has stopped. In very rare cases, they may be serious or fatal.

Acticam should not be administered to pregnant or lactating animals as the safety of the product has not been established in these cases. Acticam should also not be used in animals suffering from gastrointestinal or hemorrhagic disorders and impaired renal or hepatic function, animals with known hypersensitivity to NSAIDs, and animals less than 6 weeks of age or in cats of less than 2 kg.

An oral follow-up therapy using meloxicam or other NSAIDs should not be used in cats, as no safe dosage for repeated oral administration has been established.

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

People with known hypersensitivity (allergic) to meloxicam should avoid contact with the product.

Accidental self-injection may give rise to pain.

If the product is swallowed by a person, the advice of a doctor should be sought immediately.

In case of accidental self-injection, medical advice should be sought immediately showing the package leaflet or the label to the physician.

Why has Acticam been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) considered that, in accordance with European Union requirements, Acticam has been shown to be bioequivalent to Metacam

1.5 mg/ml oral suspension. The CVMP concluded that the benefits of Acticam exceed the risks for the alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders, reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery in dogs and reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery in cats and recommended that Acticam be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Acticam:

The European Commission granted a marketing authorisation valid throughout the European Union, for Acticam on 9 December 2008. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in January 2012.