EMA/499888/2010
EMEA/V/C/151

EPAR summary for the public

Meloxoral

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 Meloxoral?

Meloxoral is presented as a pale yellow oral suspension which is to be given mixed with food or directly into the mouth in dogs or cats. Meloxoral contains the active substance meloxicam in a strength of 0.5 mg/ml (cats) or 1.5 mg/ml (dogs) for the oral suspension. Meloxoral is a 'generic' which means that Meloxoral is similar to a 'reference veterinary medicine' already authorised in the EU (Metacam). Studies have been carried out to prove that Meloxoral is 'bioequivalent' to the reference veterinary medicine which means that Meloxoral is equivalent to Metacam in the way it is absorbed and used by the body.

What is Meloxoral used for?

Meloxoral is used in dogs to relieve inflammation and pain in musculo-skeletal disorders. It can be used for both acute disorders, such as those seen after an injury, and chronic (long term) disorders. In cats Meloxoral is used to alleviate inflammation and pain in chronic musculo-skeletal disorders.

How does Meloxoral work?

Meloxoral 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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

prostaglandins are substances that trigger inflammation, pain, exudation and fever, meloxicam reduces those responses.

How has the effectiveness of Meloxoral been studied?

Studies looked at how Meloxoral was absorbed and its effects in the body, in comparison with Metacam.

What are the side-effects of Meloxoral?

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

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 Meloxoral. If the product is swallowed by a person, the advice of a doctor should be sought immediately. In the case of accidental ingestion medical advice should be sought immediately, showing the package leaflet or label to the physician.

Why has Meloxoral been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) considered that, in accordance with European Union requirements, Meloxoral has been shown to be bioequivalent to Metacam. Therefore the CVMP's view was that, as for Metacam, Meloxoral's benefits are greater than its risks to alleviate inflammation and pain in musculo-skeletal disorders and they recommended that Meloxoral should be given a marketing authorisation.

The benefit-risk balance may be found in module 6 of this EPAR.

Other information about Meloxoral:

The European Commission granted a marketing authorisation valid throughout the European Union, for Meloxoral to LeVet B.V. on 19/11/2010. Information on the prescription status of this product may be found on the label of the carton.

This summary was last updated: 19/11/2010