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Melosus (*meloxicam*)[1]

An overview of Melosus and why it is authorised in the EU

What is Melosus and what is it used for?

Melosus is an anti-inflammatory medicine used in dogs, cats and guinea pigs.

Dogs

In dogs, Melosus is used to lessen inflammation and pain in musculo-skeletal disorders.

Cats

In cats, Melosus is used to reduce pain and inflammation after orthopaedic and minor soft tissue surgery. Moreover, it is used to lessen pain and inflammation in chronic musculo-skeletal disorders.

Guinea pigs

In guinea pigs Melosus is used to reduce pain after soft tissue surgery such as castration.

Melosus contains the active substance meloxicam and is a 'generic medicine'. This means that Melosus contains the same active substance and works in the same way as a 'reference medicine' already authorised in the European Union (EU) called Metacam.

How is Melosus used?

Melosus is available as an oral (taken by mouth) suspension as 0.5 mg/ml for use in cats and guinea pigs and 1.5 mg/ml for use in dogs. The dose depends on the animal, the bodyweight and condition and is given mixed with food or directly into the mouth for dogs and cats and directly into the mouth for guinea pigs.

Melosus can only be obtained with a prescription. For further information about using Melosus, see the package leaflet or contact your veterinarian or pharmacist.

[1] Previously known as Melocam.

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How does Melosus work?

Melosus 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 trigger inflammation, pain, exudation (fluid that leaks out of blood vessels during an inflammation) and fever, meloxicam reduces these signs of inflammation.

How has Melosus been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Metacam, and do not need to be repeated for Melosus.

As for every medicine, the company provided studies on the quality of Melosus. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Melosus?

Because Melosus is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

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

Safety information has been included in the summary of product characteristics and the package leaflet for Melosus, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers. The precautions are the same as for the reference medicine since Melosus is a generic medicine.

Why is Melosus authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Melosus has been shown to have comparable quality and to be bioequivalent to Metacam. Therefore, the Agency's view was that, as for Metacam, the benefit of Melosus outweighs the identified risk and it can be authorised for use in the EU.

Other information about Melosus

Melosus received a marketing authorisation valid throughout the EU on21 February 2011.

Further information on Melosus can be found on the Agency's website: ema.europa.eu/medicines/veterinary/EPAR/melosus.

Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in December 2018.