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EPAR summary for the public

Meloxidolor

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 Meloxidolor?

Meloxidolor is a medicine that contains the active substance meloxicam. It is available as a solution for injection (5 mg/ml, 20 mg/ml and 40 mg/ml).

Meloxidolor is a 'generic'. This means that Meloxidolor is similar to a 'reference veterinary medicine' containing the same active substance, but it is also available at a higher strength. While the reference medicine, Metacam, is available as 5 mg/ml and 20 mg/ml solutions for injection, Meloxidolor is also available as a 40 mg/ml solution for injection.

What is Meloxidolor used for?

Meloxidolor solution for injection (5 mg/ml) can be used to relieve inflammation and pain in dogs following surgery involving the bones or soft tissue (tissue just below the skin), and in cats following ovariohysterectomy (spaying) and minor soft tissue surgery.

Meloxidolor solution for injection (5 mg/ml and 20 mg/ml) is used in pigs to reduce the symptoms of lameness (inability to walk normally) and inflammation in non-infectious locomotor disorders (diseases that affect the ability to move). The 5 mg/ml solution for injection can also be used for the relief of post-operative pain associated with minor soft tissue surgery such as castration (surgical removal of the testicles) and the 20 mg/ml solution for injection can be used together with appropriate antibiotic therapy for the treatment of diseases that occur after farrowing (giving birth) such as puerperal

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septicaemia (bacteria present in blood) and toxaemia (a toxic state) (mastitis-metritis-agalactia syndrome).

Meloxidolor solution for injection (5 mg/ml, 20 mg/ml and 40 mg/ml) is used in cattle, together with appropriate antibiotic therapy, to reduce signs of disease in acute respiratory infections (infection of the lungs and airways). It can be used in combination with oral re-hydration therapy for diarrhoea (medicines given by mouth to restore water levels in the body) in calves of over one week of age and in young, non-lactating cattle. The 20 mg/ml and 40/mg/ml solutions for injection are also used in combination with antibiotic therapy to treat acute mastitis (inflammation of the udder).

Meloxidolor solution for injection (20 mg/ml and 40 mg/ml) is used in horses to relieve colic (abdominal pain) and the inflammation and pain in musculo-skeletal disorders.

How does Meloxidolor work?

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

How has Meloxidolor been studied?

For intravenous use no studies in animals were needed as Meloxidolor contains the same active substance as the reference medicine Metacam. For subcutaneous and intramuscular use no studies were need for the 5 mg/ml and 20 mg/ml strengths as they contain the same concentration of active substance and have a similar composition to the reference product Metacam.

What benefit has Meloxidolor shown during the studies?

As Meloxidolor is considered to be bioequivalent to the reference medicine, its benefit is taken as being the same as that of the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What is the risk associated with Meloxidolor?

Side effects sometimes seen with other NSAIDs, such as loss of appetite, vomiting, diarrhoea, blood appearing in the stools, renal (kidney) failure and apathy (lack of vitality) are occasionally seen with Meloxidolor in dogs and cats. In dogs, these generally occur within the first week of treatment and usually disappear once treatment has stopped. In very rare cases they may be serious or fatal.

A slight temporary swelling at the injection site following injection under the skin was observed in cattle and pigs. In horses, a temporary swelling at the injection site can occur but resolves without intervention.

In very rare cases, potentially serious or fatal anaphylactoid reactions (similar to severe allergic reactions) may occur following administration of the solution for injection and should be treated symptomatically.

Meloxidolor must not be used in animals with liver, heart or kidney problems, bleeding disorders, or suffering from irritation or ulcers of the digestive tract. It must not be used in animals which are hypersensitive (allergic) to the active substance or to any of the other ingredients.

Meloxidolor should not be used in pregnant or lactating dogs, cats and horses, but it can be used during pregnancy and lactation for cattle and pigs.

Meloxidolor must not be used in dogs, in cats or horses less than six weeks of age, in cattle less than one week of age when used in the treatment of diarrhoea or in pigs less than two days old. It must not be used in cats weighing less than 2 kg.

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 Meloxidolor. If someone accidentally injects themselves with the medicine, the advice of a doctor should be sought immediately.

Pregnant women and women of child-bearing potential should not administer Meloxidolor as meloxicam may be harmful for the foetus and unborn child.

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.

Cattle

For meat the withdrawal period is 15 days and for milk it is five days.

Pigs

For meat the withdrawal period is five days.

Horses

For meat the withdrawal period is five days. The product is not authorised for use in horses producing milk for human consumption.

Why has Meloxidolor been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) considered that, in accordance with European Union requirements, Meloxidolor has been considered to be bioequivalent to Metacam. Therefore the CVMP's view was that, as for Metacam, Meloxidolor's benefits are greater than its risks when used for the approved indications and the Committee recommended that Meloxidolor be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Meloxidolor:

The European Commission granted a marketing authorisation valid throughout the European Union, for Meloxidolor on 22/04/2013. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 22/04/2013.