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EPAR summary for the public

Contacera

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 Contacera?

Contacera is a medicine that contains the active substance meloxicam. It is available as a solution for injection (20 mg/ml) and an oral suspension (15 mg/ml).

Contacera is a 'generic', which means that Contacera is similar to a 'reference veterinary medicine' already authorised in the EU (Metacam).

What is Contacera used for?

Contacera is used in cattle, together with appropriate antibiotic therapy, to reduce clinical signs of disease in acute respiratory infection (infection of the lungs and airways) and to treat acute mastitis (inflammation of the udder). It can be used for diarrhoea in combination with oral re-hydration therapy (medicines given by mouth to restore water levels in the body) to reduce clinical signs of the disease in calves of over one week of age and young, non-lactating cattle. It can be used for the relief of post-operative pain following dehorning in calves.

In pigs, Contacera is used to reduce the symptoms of lameness and inflammation in non-infectious locomotor disorders (diseases that affect the ability to move) and for supportive therapy together with appropriate antibiotic therapy in the treatment of diseases that occur after farrowing (giving birth) such as puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome). Septicaemia and toxaemia are conditions where bacteria circulate in the blood and produce harmful substances (toxins).

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In horses, Contacera is used for the relief of pain associated with colic (abdominal pain) and for the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders.

How does Contacera work?

Contacera 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 Contacera been studied?

Since Contacera is a generic medicine, studies have been conducted to show that Contacera has the same characteristics as the reference medicine, Metacam.

What benefit has Contacera shown during the studies?

Based on the findings of the studies, Contacera was considered to be bioequivalent to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body. Consequently, Contacera's benefit is taken as being the same as that of the reference medicine.

What is the risk associated with Contacera?

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. Side effects that occurred with the oral suspension in horses included isolated cases of adverse reactions typically associated with NSAIDs (slight urticaria and diarrhoea). Symptoms were reversible. In very rare cases loss of appetite, lethargy, abdominal pain and colitis (inflammation of the lower part of the gut) have been reported.

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

Contacera 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.

Contacera should not be used in pregnant or lactating mares but it can be used during pregnancy and lactation for cattle and pigs.

Contacera must not be used in horses less than six weeks of age or in cattle less than one week of age when used in the treatment of diarrhoea.

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 with the 20 mg/ml solution for injection is five days and with the 15 mg/ml oral suspension it is three days.

The product is not authorised for use in horses producing milk for human consumption.

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

Why has Contacera been approved?

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

Other information about Contacera:

The European Commission granted a marketing authorisation valid throughout the European Union, for Contacera on 6 December 2012. Information on the prescription status of this product may be found on the label of the carton.

This summary was last updated in December 2013.