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EPAR summary for the public

Previcox

Firocoxib

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 Previcox?

Previcox contains the active substance firocoxib, which belongs to a class of medicines having anti-inflammatory action. Previcox is presented as chewable tablets for dogs (57 mg and 227 mg) and as an oral paste for horses (8.2 mg/g).

What is Previcox used for?

Previcox is used for a relief of pain and inflammation associated with osteoarthritis, soft-tissue, orthopaedic and dental surgery in dogs and for the alleviation of pain and inflammation associated with osteoarthritis and reduction of associated lameness in horses.

The dose, duration of treatment and frequency will depend on the weight and type of animal and condition to be treated. For details, please see the Package Leaflet.

How does Previcox work?

Previcox contains firocoxib, which belongs to a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) belonging to the Coxib group, which acts by selective inhibition of

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cyclooxygenase-2 (COX-2). Coxibs display pain relief, anti-inflammatory and antipyretic properties. Firocoxib blocks the enzyme (cyclo-oxygenase) that is involved in the production of prostaglandins. As the prostaglandins are substances that trigger pain, inflammation and fever, Previcox, therefore, reduces those responses.

How has Previcox been studied?

Previcox has been studied in laboratory animals, as well as in dogs and horses that were treated in various veterinary practices/clinics across Europe ("clinical studies").

Dog:

Previcox chewable tablets for dogs were studied in two large European field studies in dogs for a period of up to 90 days. The results showed an improvement in lameness score in dogs with established osteoarthritis. The product was shown to be comparable to other reference products (carprofen and meloxicam, respectively).

Horse:

Two multi-centre studies were conducted (one in the US and one in Europe) to investigate the efficacy, safety and acceptability of firocoxib under field conditions when administered to horses orally once daily for 14 days at a dose of 0.1 mg/kg. The CVMP concluded that Previcox oral paste was as effective as other authorised products (phenylbutazone and vedaprofen) in the alleviation of pain and inflammation associated with osteoarthritis and the reduction of associated lameness in horses.

What benefit has Previcox shown during the studies?

Previcox tablets for dogs improved the scores for the relief of pain and inflammation. Administration of the product in accordance with the recommended dosing schedule for a period of up to 90 days resulted in an improvement in lameness score in dogs with established osteoarthritis.

Previcox oral paste administered once daily for 14 days at a dose of 0.1 mg/kg improved clinical scores for lameness and soft tissue injuries in horses and also helped alleviate pain and inflammation associated with osteoarthritis in horses.

What is the risk associated with Previcox?

The side effects of Previcox are typical for those seen with other medicines in this product class (NSAIDs) such as oral lesions (tissue damage) in the mouth of horses, soft faeces/diarrhoea or lethargy. These reactions are generally of a transitory nature and are reversible when the treatment is stopped.

Previcox must not be administered with corticosteroids or other NSAIDs. Care should also be taken when used with molecules displaying action on renal flow e.g. diuretics.

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

In case of accidental ingestion, it is necessary to seek medical advice immediately and show the package leaflet or the label to the physician.

Avoid contact with eyes and skin. If it occurs, rinse affected area immediately with water.

Wash hands after use of the product.

Return halved tablets to the blister and keep out of the reach of children.

Women of child-bearing age should avoid contact with, or wear disposable gloves, when administering the product.

What is the withdrawal period?

The withdrawal period is the time allowed after administration of the medicine and before the animal can be slaughtered and the meat or milk used for human consumption.

After the last day of treatment with Previcox, horses should not be slaughtered for 26 days (when treated with the oral paste). The use of Previcox is not permitted in mares producing milk for human consumption.

Why has Previcox been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) decided that the benefits of Previcox are greater than any risks of treatment and they recommended that Previcox should be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Previcox:

The European Commission granted a marketing authorisation valid throughout the European Union for Previcox on 13 September 2004. Information on the prescription status of this product may be found on the label of the carton.

This summary was last updated in April 2012.