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EPAR summary for the public

Equioxx

firocoxib

This is a summary of the European public assessment report (EPAR) for Equioxx. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use Equioxx.

For practical information about using Equioxx, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is Equioxx and what is it used for?

Equioxx is a medicine used in horses to relieve pain and inflammation in the joints caused by osteoarthritis (a long-term disease causing damage and pain in the joints) and to reduce the lameness that is associated with the disease. It contains the active substance firocoxib.

How is Equioxx used?

Equioxx is available as a solution for injection, an oral paste and chewable tablets. Treatment is once daily. The solution for injection is given into a vein while the paste and tablets are given by mouth. The dose depends on the bodyweight of the animal except for the tablets which are for horses of 450 to 600 kg bodyweight and where the dose is one tablet. The overall duration of treatment depends on the horse's response, but should not exceed 14 days. Equioxx can only be obtained with a prescription.

For further information, see the package leaflet.

How does Equioxx work?

The active substance in Equioxx, firocoxib, is a non-steroidal anti-inflammatory drug (NSAID) that belongs to the group of medicines called 'cyclo-oygenase-s (COX-2) inhibitors' (or Coxibs). It blocks the COX-2 enzyme, resulting in a reduction in the production of prostaglandins, substances that are involved in the inflammation process. By reducing the production of prostaglandins, Equioxx helps reduce the responses of inflammation, including pain.

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What benefits of Equioxx have been shown in studies?

Two field studies investigated the effectiveness of Equioxx oral paste in treating horses with lameness of more than 4 weeks due to osteoarthritis. One study in the USA compared Equioxx to another NSAID medicine, phenylbutazone, and the second study in Europe compared Equioxx to the NSAID vedaprofen. The studies showed that Equioxx oral paste given daily for 14 days was as effective as the comparator medicines.

Equioxx oral paste and Equioxx solution for injection have been studied in a laboratory and found to be bioequivalent. Similarly Equioxx oral paste and Equioxx chewable tablets have been shown to be bioequivalent. Two forms of a medicine are bioequivalent when they produce the same levels of active substance in the body. This means that the solution for injection and the chewable tablets can be expected to produce similar results to the oral paste.

What are the risks associated with Equioxx?

The most common side effects with Equioxx (which may affect more than 1 in 10 horses) are ulcers or sores of the lining of the mouth or the skin around the mouth. These are typically mild and resolve without treatment.

The most common side effects with Equioxx (which may affect up to 1 in 100 horses) are salivation and lip and tongue swelling associated with the mouth sores.

Equioxx must not be used in horses suffering from stomach or gut disorders and bleeding, nor in case of reduced liver, heart or kidney function or bleeding disorders.

Equioxx must not be used in breeding, pregnant or lactating horses.

Equioxx must not be used at the same time as corticosteroid medicines or other NSAIDs.

For the full list of all side effects reported with Equioxx and the full list of restrictions, see the package leaflet.

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 Equioxx, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

People should avoid contact of the medicine with eyes and skin and wash their hands after handling the product.

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

If the medicine is accidentally swallowed or someone accidentally injects themselves, the advice of a doctor should be sought immediately and the package leaflet or label shown to the doctor.

What is the withdrawal period in food-producing animals?

The withdrawal period is the time required after administration of a medicine before an animal can be slaughtered and the meat used for human consumption.

The withdrawal period for meat from horses treated with Equioxx is 26 days.

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

Why is Equioxx approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Equioxx's benefits are greater than its risks and recommended that it be approved for use in the EU.

Other information about Equioxx:

The European Commission granted a marketing authorisation valid throughout the EU for Equioxx on 25 June 2008.

This authorisation was based on the authorisation granted to Previcox in 2004 ('informed consent').

The full EPAR for Equioxx can be found on the Agency's website: ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports. For more information about treatment with Equioxx, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in December 2016.