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EPAR summary for the public

Novaquin

Meloxicam

This is a summary of the European public assessment report (EPAR) for Novaquin. 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 Novaquin.

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

What is Novaquin and what is it used for?

Novaquin is a veterinary medicine used for the alleviation of inflammation and relief of pain and chronic musculoskeletal disorders (disorders affecting the muscle and bones) in horses. It contains the active substance meloxicam.

Novaquin is a 'generic medicine'. This means that Novaquin is similar to a 'reference medicine' already authorised in the European Union (EU) called Metacam.

For further information, see the package leaflet.

How is Novaquin used?

Novaquin is available as a 15 mg/ml oral suspension and can only be obtained with a prescription. It is given once daily for up to two weeks. It is either given with food or directly into the mouth at a dosage of 0.6 mg/kg bodyweight.

For further information, see the package leaflet.

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How does Novaquin work?

Novaquin contains meloxicam, which belongs to a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Meloxicam acts by blocking an enzyme called cyclooxygenase 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 inflammation) and fever, meloxicam reduces these signs of disease.

How has Novaquin been studied?

Because Novaquin is a generic medicine, studies in animals have been limited to tests to determine that it is bioequivalent to the reference medicine, Metacam. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Novaquin?

Because Novaquin 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 Novaquin, including the precautions to be followed by healthcare professionals and animal owners or keepers. The precautions are the same as for the reference medicine since Novaquin is a generic medicine.

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. It is also the time required after administration of a medicine before milk or eggs may be used for human consumption.

The withdrawal period for meat from horses treated with Novaquin is three days.

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

Why is Novaquin approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that, in accordance with EU requirements, Novaquin has been shown to have comparable quality and to be bioequivalent to Metacam. Therefore, the CVMP's view was that, as for Metacam, the benefits outweigh the identified risks. The Committee recommended that Novaquin be approved for use in the EU.

Other information about Novaquin

The European Commission granted a marketing authorisation valid throughout the EU for Novaquin on 8 September 2015.

The full EPAR for Novaquin 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 Novaquin, read the package leaflet (also part of the EPAR) or contact your veterinarian or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in July 2015.