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EPAR summary for the public

Quadrisol

vedaprofen

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

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

What is Quadrisol and what is it used for?

Quadrisol is a veterinary medicine used in horses to relieve pain and reduce inflammation due to injury to the muscle, bones and joints as well as to other non-bony areas of the body (so called soft tissue lesions). Quadrisol can also be used to relieve pain and reduce inflammation after an operation. It contains the active substance vedaprofen.

How is Quadrisol used?

Quadrisol, available as an oral (mouth) gel, is given twice daily before feeding for a maximum of two weeks. When used before an operation it is given at least 3 hours before the operation and treatment may be continued for up to one week. The amount of gel given in each dose is adjusted depending on the weight of the animal.

The medicine can only be obtained with a prescription

For further information, see the package leaflet.

How does Quadrisol work?

Quadrisol contains vedaprofen, which belongs to a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Vedaprofen blocks an enzyme called cyclooxygenase which is involved in the production of prostaglandins. As prostaglandins are substances that trigger inflammation, pain, and fever, vedaprofen reduces these signs of injury.

What benefits of Quadrisol have been shown in studies?

Quadrisol has been studied in both laboratory and field studies. This included studies in a large number of horses with bone, muscle and other soft tissue and joint problems. Quadrisol oral gel improved lameness and soft tissue injuries in horses and the response to treatment with Quadrisol was similar to the response to either flunixin meglumine or phenylbutazone, which are other NSAIDs used to treat these conditions.

What are the risks associated with Quadrisol?

The side effects of Quadrisol are typical for those seen with other medicines from this product class (NSAIDs) such as lethargy or damage to (lesions) the mouth, stomach, intestines (including soft stools or diarrhoea) and kidneys. In horses, skin rashes (urticaria) have been reported. Side effects are generally reversible once the medicine is stopped.

Quadrisol must not be given to horses with stomach and gut disorders or to horses with reduced heart, liver and kidney function. It must not be given to foals aged less than six months or to mares producing milk.

For 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?

In case of accidental self-injection, medical advice 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. It is also the time required after administration of a medicine before milk may be used for human consumption.

The withdrawal period for meat from horses treated with Quadrisol is 12 days. The medicine is not authorised for use in horses producing milk for human consumption.

Why is Quadrisol approved?

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

Other information about Quadrisol:

The European Commission granted a marketing authorisation valid throughout the EU for Quadrisol on 4 December 1997.

The full EPAR for Quadrisol 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 Quadrisol, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in April 2017.