



EUROPEAN MEDICINES AGENCY
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EPAR summary for the public

TROCOXIL

Mavacoxib

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 Trocoxil?

Trocoxil contains the active substance mavacoxib, which belongs to a class of medicines with anti-inflammatory action. It is available as triangular chewable tablets, in five different strengths (6, 20, 30, 75 and 95 mg).

What is Trocoxil used for?

Trocoxil is used for the treatment of pain and inflammation associated with degenerative joint disease (disease involving damage to the joints, such as osteoarthritis) in dogs at least one year of age. It is used when continuous treatment for more than one month is needed.

Trocoxil is given at a dose of 2 mg per kilogram body weight, immediately before or with the dog's main meal. There should be a gap of two weeks between the first and second doses, after which it is given once a month. The dose and duration of treatment (maximum 6.5 months) will depend on the weight and type of animal and condition to be treated. For details, please see the Package Leaflet.

How does Trocoxil work?

The active substance in Trocoxil, mavacoxib, belongs to a class of medicines called non steroidal anti-inflammatory drugs (NSAIDs). It works by blocking an enzyme called cyclo oxygenase 2 (COX 2). This enzyme is involved in producing substances called prostaglandins, which are involved in pain and



inflammation. By blocking the production of prostaglandins, Trocoxil reduces the pain and inflammation caused by damage to the joints.

How has Trocoxil been studied?

Trocoxil has been studied in laboratory animals, as well as in dogs that were treated in various veterinary practices and clinics across Europe (“clinical studies”).

Trocoxil chewable tablets for dogs were studied in one main study in dogs with osteoarthritis. The medicine was compared with carprofen (another NSAID) for up to 6.5 months and long term effects of treatment were also studied. Dogs of both sexes and various breeds were included in the study. The results showed an improvement in lameness score in dogs with established osteoarthritis. The product was shown to be comparable to the reference product (carprofen).

What benefit has Trocoxil shown during the studies?

Trocoxil tablets for dogs improved pain relief and inflammation. Administration of the product in accordance with the recommended monthly dosing schedule for a period of up to 6.5 months resulted in an improvement in lameness and quality of life in dogs with established osteoarthritis, as assessed by the dogs’ owners. Compliance to treatment was better with Trocoxil, possibly because it is given once a month rather than every day.

What is the risk associated with Trocoxil?

The side effects of Trocoxil are similar to those seen with other medicines in this product class (NSAIDs) and include loss of appetite, soft faeces/diarrhoea, vomiting, apathy (lack of interest in surroundings) and signs of kidney problems. If a dog experiences these side effects, treatment should be stopped and general supportive therapy should be given as appropriate for NSAID overdose.

Trocoxil must not be used in dogs aged less than one year or weighing less than 5 kg. It must not be used in dogs with problems affecting the stomach or gut, including ulcers or bleeding, or in dogs that have signs of bleeding problems. It must not be used in dogs with kidney or liver problems, or inadequate blood flow to the heart muscle, or in dogs that are pregnant, breeding or lactating. It must also not be used in dogs that are hypersensitive (allergic) to mavacoxib, any of the other ingredients in the tablet or sulphonamides. It must not be used with glucocorticosteroids or other NSAIDs.

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

Ingestion of Trocoxil may be harmful for children. To avoid accidental ingestion, give the tablet to the dog immediately after it is removed from the blister packaging. People with a known allergy to NSAIDs should avoid contact with Trocoxil.

Do not eat, drink, or smoke when handling Trocoxil. Wash hands after handling the medicine.

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

Why has Trocoxil been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Trocoxil exceed the risks for the treatment of pain and inflammation associated with degenerative joint disease in dogs in cases where continuous treatment exceeding one month is indicated, and

recommended that Trocoxil be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Trocoxil:

The European Commission granted a marketing authorisation valid throughout the European Union, for Trocoxil on 09/09/2008. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in: 04-2013.