



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/532732/2010
EMA/V/C/000162

EPAR summary for the public

Cimalgex

cimicoxib

This document is a summary of the European Public Assessment Report (EPAR). 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 Cimalgex?

Cimalgex is a veterinary medicine that contains cimicoxib. It is available as oblong chewable tablets, in three different strengths (8 mg, 30 mg and 80 mg).

What is Cimalgex used for?

Cimalgex is used in dogs to treat the pain and inflammation associated with osteoarthritis (a long term disease causing damage and pain in the joints). It is also used for the management of pain and inflammation associated with surgery to the bones or soft tissues (such as muscles).

When used for osteoarthritis, the tablets are given to the dog once a day, with or without food, at a dose of 2 mg/kg body weight, using the appropriate tablet(s) according to the dog's weight. Dogs can be treated for up to six months. For longer-term treatment, regular monitoring should be undertaken by the veterinary surgeon.

When used with surgery, the tablets are given to the dog around two hours before the start of the operation at a dose of 2 mg/kg body weight, using the appropriate tablet(s) according to the dog's weight, and then once a day for the following three to seven days, based on the judgment of the veterinary surgeon.



How does Cimalgex work?

The active substance in Cimalgex, cimicoxib, belongs to a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). It works mainly 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, cimicoxib reduces the pain and inflammation caused by osteoarthritis or surgery on the bones or soft tissues.

How has Cimalgex been studied?

Cimalgex has been studied in laboratory animals, as well as in dogs that were treated in various veterinary practices and clinics across Europe ("field studies") in which Cimalgex was compared with other licensed veterinary NSAID medicines. These field studies involved dogs of different age groups, genders and breeds.

A study in dogs (average age 8.8 years old) with chronic osteoarthritis lasted for up to 90 days. Once a day the dogs were given either Cimalgex or firocoxib, a medicine authorised for use for this condition. The effectiveness was determined based on both examinations by a veterinarian and assessments by the animal's owner of some signs of osteoarthritis (such as lameness, pain or difficulty moving).

A second study involved dogs (various ages from four months upwards) undergoing either orthopaedic or soft tissue surgery. The dogs received either Cimalgex or a comparator product (carprofen). The first dose was given two hours before surgery, and treatment was continued for several days. Pain was assessed by the veterinarian (up to 24 hours after surgery and at the end of the follow-up treatment). The owner also noted pain-related observations.

What benefit has Cimalgex shown during the studies?

Given daily, Cimalgex reduced pain and inflammation (and the signs of these, such as lameness) in dogs with chronic osteoarthritis, and was as effective as the comparator NSAID, firocoxib.

Cimalgex was also shown to be as effective as the comparator NSAID, carprofen, in the management of peri-operative pain due to orthopaedic or soft tissue surgery during the first 24 hours after surgery.

What is the risk associated with Cimalgex?

The most common side effects with Cimalgex are mild and transient vomiting or diarrhoea. For a full list of all side-effects reported with Cimalgex, see the Package Leaflet.

Cimalgex must not be used in dogs aged less than 10 weeks old, and if the dog is less than 6 months of age careful monitoring by the veterinarian is recommended. Cimalgex should not be used in dogs that are pregnant, breeding or lactating, or in dogs with problems affecting the stomach or gut, including ulcers or bleeding, or in dogs that have signs of bleeding problems. Cimalgex must also not be used in dogs that are hypersensitive (allergic) to cimicoxib or any of the other ingredients in the tablets. It must not be used together with corticosteroids or other NSAIDs.

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

Cimicoxib may cause skin sensitisation and people should wash their hands after handling the tablets. People with a known hypersensitivity (allergy) to cimicoxib should avoid contact with Cimalgex tablets.

In case of accidental ingestion, medical advice should be sought immediately and the package leaflet or the label shown to the doctor.

Why has Cimalgex been approved?

The CVMP decided that the benefits of Cimalgex are greater than its risks for the treatment of pain and inflammation associated with osteoarthritis, and the management of peri-operative pain due to orthopaedic or soft tissue surgery, and recommended that Cimalgex be given a marketing authorisation. The benefit-risk balance may be found in the Scientific Discussion part of this EPAR.

Other information about Cimalgex:

The European Commission granted a marketing authorisation valid throughout the European Union, for Cimalgex to Vétoquinol SA on 18/02/2011. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 18/02/2011.