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EPAR summary for the public

Procox

emodepside / toltrazuril

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 Procox?

Procox is an antiparasitic medicine that contains two active substances, emodepside and toltrazuril. It is available as an oily suspension, containing 0.9 mg/ml emodepside and 18 mg/ml toltrazuril.

What is Procox used for?

Procox is used to treat dogs which are infected, or which the veterinary surgeon suspects of being infected, by two types of parasite at the same time, roundworms and coccidia. The full list of roundworms and coccidia against which Procox is effective can be found in the summary of product characteristics (SPC).

Procox is given as a single treatment. The dose depends on the body weight of the dog being treated. The standard dose of the oral suspension is 0.5 ml per kg bodyweight.

How does Procox work?

The two active substances in Procox interact with different parts of the parasites systems. Emodepside interferes with certain specific receptors in the nervous systems of roundworms, which results in their subsequent paralysis and death. Toltrazuril interferes with the enzymes needed by the coccidia toproduce energy. As a result it is able to kill the parasites at all stages of their development.

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How has Procox been studied?

The company presented the results of studies across Europe in dogs looking at the effectiveness of Procox against the specified roundworms and coccidia. The studies included dogs of various ages, different breeds and weights, which were naturally infected, or could become infected, with parasitic gastrointestinal roundworms or coccidia.

The effectiveness of Procox against roundworms was studied by looking at the number of worm eggs passed out in the animal's faeces after a single treatment with the recommended dose, and compared with a medicine (containing milbemycin oxime and praziquantel) commonly used for the treatment of these roundworm infections.

The effectiveness of the product in coccidial infections was studied by looking at the number of oocysts (egg-like structures that mature into the infective stage of the parasite) passed out in the animal's faeces. One study compared Procox with sulfadimethoxine in the treatment of coccidiosis and the other with no treatment in the prevention of the disease.

What benefit has Procox shown during the studies?

The studies showed that Procox was superior to the comparator medicines or placebo in all studies. Procox is well tolerated in dogs with mild, transient, gastro-intestinal disturbances, including vomiting, being observed.

What is the risk associated with Procox?

The most common side effects in dogs are slight and temporary digestive system disorders such as vomiting or loose stools.

Procox must not be used in puppies under two weeks of age or in dogs or puppies weighing less than 0.4 kg. The product must also not be used in cases of hypersensitivity (allergy) to either of the active substances or to any of the other ingredients.

It is not recommended to use Procox in young puppies of Collie or related breeds since it has not been investigated whether these dogs are more sensitive to treatment with emodepside.

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

The person administering Procox should avoid contact with their skin or eyes. If accidental exposure occurs, the eyes should be rinsed immediately with plenty of water, or the skin washed with soap and water. People should not eat, drink or smoke while handling Procox, and should wash their hands after use.

If Procox is swallowed accidentally, medical advice should be sought immediately and the package leaflet or label shown to the doctor. For more information, see the package leaflet.

Why has Procox been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Procox outweigh the risks when used for the approved indications and recommended that Procox be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Procox:

The European Commission granted a marketing authorisation valid throughout the European Union, for Procox on 20/04/2011. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in November 2012.