9 February 2011
EMA/CVMP/533373/2010
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

Procox

emodepside & toltrazuril

On 9 February 2011, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,[2] recommending the granting of a marketing authorisation for the veterinary medicinal product Procox oral suspension for dogs. The product is indicated for use when mixed parasitic infections caused by certain specified roundworms and coccidia are suspected or demonstrated.

The applicant for this veterinary medicinal product is Bayer Animal Health GmbH.

The two active substances in Procox are emodepside (0.9 mg/ml) and toltrazuril (18 mg/ml). Emodepside is a depsipeptide antiparasiticide which acts at the neuromuscular junction by stimulating presynaptic receptors belonging to the secretin receptor family, resulting in paralysis and death of the parasites. Toltrazuril is an anticoccidial which acts against all intracellular development stages of the coccidia, resulting in their death.

The benefits of Procox are its efficacy against the replication of coccidia and the shedding of oocysts at all stages of coccidial infection. The most common side effects are slight and transient digestive tract disorders, such as vomiting or loose stools.

The approved indication is: For dogs, when mixed parasitic infections caused by roundworms and coccidia of the following species are suspected or demonstrated:

Roundworms (Nematodes):
- *Toxocara canis* (mature adult, immature adult, L4)
- *Uncinaria stenocephala* (mature adult)
- *Ancylostoma caninum* (mature adult)

Coccidia:
- *Isospora ohioensis* complex
- *Isospora canis*

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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Procox is effective against the replication of *Isospora* and also against the shedding of oocysts. Although treatment will reduce the spread of infection, it will not be effective against the clinical signs of infection in already infected animals.

Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Procox and therefore recommends the granting of the marketing authorisation.