14 October 2011
EMA/CVMP/760936/2011
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

Panacur AquaSol

Fenbendazole

On 13 October 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 Panacur AquaSol, 200 mg/ml suspension for use in drinking water, intended for the treatment and control of gastro-intestinal nematodes in pigs. The applicant for this veterinary medicinal product is Intervet International BV.

The active substance of Panacur AquaSol is fenbendazole, an anthelminthic medicinal product, ATCvet code QP52AC13, which acts by interfering with the energy metabolism of the nematode.

The benefits of Panacur AquaSol are its value in the treatment and control of infections with *Ascaris sum* and *Oesophagostomum* spp. Panacur AquaSol is well tolerated in pigs with no adverse effects being observed. For the user, skin exposure may lead to allergic reactions.

The approved indication is: "Treatment and control of gastro-intestinal nematodes in pigs infected with:

- *Ascaris suum* (adult, intestinal and migrating larval stages)
- *Oesophagostomum* spp (adult stages)

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 Panacur AquaSol and therefore recommends the granting of the marketing authorisation.

[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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