



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/834845/2011
EMA/V/C/002008

EPAR summary for the public

Panacur AquaSol

fenbendazole

This is a summary of the European public assessment report (EPAR) for Panacur AquaSol. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use Panacur AquaSol.

For practical information about using Panacur AquaSol, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is Panacur AquaSol and what is it used for?

Panacur AquaSol is used for the treatment and control of three types of roundworm infections in the gut of pigs:

- *Ascaris suum* (adult intestinal and migrating larval stages);
- *Oesophagostomum* worms (adult stages);
- *Trichuris suis* (adult stages).

Panacur AquaSol is also used for the treatment of three types of roundworm infections in the gut of chickens:

- *Ascaridia galli* (L5 larvae and adult stages);
- *Heterakis gallinarum* (L5 larvae and adult stages);
- *Capillaria* worms (L5 larvae and adult stages).

How is Panacur AquaSol used?

Panacur AquaSol is available as an oral suspension (200 mg/ml) for use in drinking water and can only be obtained with a prescription.



For pigs, Panacur AquaSol is added to their drinking water in a quantity that aims to supply each pig 2.5 mg fenbendazole per kg bodyweight daily; this is done for two consecutive days for treatment and control of *Ascaris suum* and *Oesophagostomum* infections, and for three consecutive days to treat and control *Trichuris suis*. The amount added is based on the combined weight of all the pigs to be treated, with 2.5 mg added for each kg bodyweight on each treatment day (two or three consecutive days respectively).

For chickens, Panacur AquaSol is added to their drinking water in a quantity that aims to supply each chicken 1 mg fenbendazole per kg bodyweight daily for treating *Ascaridia galli* and *Heterakis gallinarum* and 2 mg fenbendazole per kg bodyweight daily for *Capillaria* infections. In both cases, treatment is for five consecutive days.

Before allowing the animals to access the medicated water, the water delivery system should be drained and flushed with the medicated water.

How does Panacur AquaSol work?

The active substance in Panacur AquaSol, fenbendazole, is a well-known anthelmintic, a substance that is active against helminths (parasitic worms). It works by interfering with the formation of tube-like structures called 'microtubules' inside the cells of the worm that are needed to perform vital functions such as growth and cell division. As a result, the cells cannot divide and eventually die.

The medicine is effective against the worms and their eggs.

What benefits of Panacur AquaSol have been shown in studies?

Panacur AquaSol was tested in three field studies involving pigs. The first study included 432 pigs infected with *Ascaris suum* and the second study included 102 pigs infected with *Oesophagostomum* species. In both studies, animals received either treatment with Panacur AquaSol or no treatment at all. After treatment with Panacur AquaSol, no *Ascaris suum* or *Oesophagostomum* eggs could be detected in the faeces of the pigs. In a third study, 254 pigs infected with *Trichuris suis* were treated either with Panacur AquaSol or received no treatment. After treatment with Panacur AquaSol, the number of *Trichuris suis* eggs was reduced by 90%.

The effectiveness of Panacur AquaSol was also investigated in a field study involving chickens bred for laying and chickens bred for meat, infected with *Ascaridia galli* or *Heterakis gallinarum*. Treatment with Panacur Aquasol at 1 mg/kg for 5 days in chickens reduced intestinal worm counts by 91% for *Ascaridia galli* and 98% for *Heterakis gallinarum*. A further field study involved chickens bred for laying and broiler breeders (chickens producing parent stock for chickens bred for meat), infected with *Capillaria* worms. Panacur AquaSol treatment at 2 mg/kg for 5 days reduced worm counts by 100%.

What are the risks associated with Panacur AquaSol?

There are currently no known side effects associated with Panacur AquaSol. Repeated use of Panacur AquaSol or a similar anthelmintic may result in resistance. The medicine should not be allowed to enter surface waters as it has harmful effects on aquatic organisms.

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

Panacur AquaSol may be toxic if ingested by humans. The person administering Panacur AquaSol should avoid contact with his/her skin, eye and moist body surfaces (mucous membranes) as the medicine may cause reactions, including skin irritation. Protective gloves must be worn at all times whilst handling the product and cleaning the measuring device. Hands should be washed after use. In case of skin or eye contact, the affected area should be rinsed immediately with water and any contaminated clothes should be removed. Pregnant women must take extra precautions when handling Panacur AquaSol as effects on the developing baby cannot be excluded.

What is the withdrawal period in food-producing animals?

The withdrawal period is the time required after administration of the medicine before the animal can be slaughtered and the meat used for human consumption. It is also the time required after administration of the medicine before eggs can be used for human consumption.

The withdrawal period for Panacur AquaSol for pig meat and offal is four days. The withdrawal period for chicken meat and offal is six days for the 1 mg fenbendazole/kg dose and nine days for the 2 mg fenbendazole/kg dose. The withdrawal period for eggs is zero days.

Why is Panacur AquaSol approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Panacur AquaSol's benefits are greater than its risks and recommended that it be approved for use in the EU.

Other information about Panacur AquaSol

The European Commission granted a marketing authorisation valid throughout the EU, for Panacur AquaSol on 09/12/2011.

The full EPAR for Panacur AquaSol can be found on the Agency's website: ema.europa.eu/Find/medicine/Veterinary_medicines/European_public_assessment_reports. For more information about treatment with Panacur AquaSol, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in January 2018.