SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Panacur AquaSol 200 mg/ml suspension for use in drinking water for pigs and chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1ml contains:

Active substances:
Fenbendazole 200 mg

Excipients:
Benzyl alcohol 20 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

White to off-white suspension for use in drinking water.
The suspension particles are in the sub-micron size range.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs and chickens

4.2 Indications for use, specifying the target species

Pigs:
Treatment and control of gastro-intestinal nematodes in pigs infected with:

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

Chickens:
Treatment of gastro-intestinal nematodes in chickens infected with:
- *Ascaridia galli* (L5 and adult stages)
- *Heterakis gallinarum* (L5 and adult stages) - *Capillaria* spp. (L5 and adult stages)

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

Parasitic resistance to any particular class of anthelmintic may develop following frequent repeated use of an anthelmintic of that class.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each flock.

4.5 Special precautions for use

Special precautions for use in animals

In the absence of available data, treatment of chicken less than 3 weeks of age should be based on a benefit/risk assessment by the responsible veterinarian.

Special precautions to be take by the person administering the veterinary medicinal product to animals

This veterinary medicinal product may be toxic to humans after ingestion. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Embryotoxic effects cannot be excluded. Pregnant women must take extra precautions when handling this veterinary medicinal product.

Avoid contact with skin, eye and mucous membranes. People with known hypersensitivity to fenbendazole should avoid contact with the veterinary medicinal product.

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product and cleaning the measuring device. Wash hands after use.

In case of accidental spillage onto skin and/or eye, immediately rinse with plenty of water. Remove contaminated clothes after spillage.

Special precautions for the protection of the environment:

The veterinary medicinal product should not enter water courses as fenbendazole may be dangerous for fish and other aquatic organisms.
Other precautions:

None

4.6 Adverse reactions (frequency and seriousness)

Pigs, chickens:
None known.
Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also section “Contact details” of the package leaflet.

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy, lactation or lay.
Laying birds:
Can be used in birds in lay.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

In drinking water use.
Underdosing could result in ineffective use and may favour resistance development.
To ensure a correct dosage, body weight should be determined as accurately as possible.
Accuracy of the dosing device should be thoroughly checked.
Before allowing animals to have access to the medicated water, the water delivery system should be drained, if possible, and flushed with the medicated water to ensure accuracy of dosing. This procedure may need to be performed on all treatment days.
Pigs:
The dose is 2.5 mg fenbendazole per kg body weight per day (equivalent to 0.0125 ml the veterinary medicinal product). For the treatment and control of *Ascaris suum* and *Oesophagostomum* spp. this dose has to be administered on 2 consecutive days. For the treatment and control of *Trichuris suis* the dose has to be administered on 3 consecutive days.
Dose calculation:
The required daily amount of veterinary medicinal product is calculated from the total estimated body weight (kg) of the entire group of pigs to be treated. Please use the following formula:
ml veterinary medicinal product/day = Total estimated body weight (kg) of pigs to be treated x 0.0125 ml
Examples:

Total body weight of pigs to be treated	**Day 1 amount of veterinary medicinal product**	**Day 2 amount of veterinary medicinal product**	**Day 3 amount of veterinary medicinal product**	**Total amount (for 2 days)**	**Total amount (for 3 days)**
80,000 kg 320,000 kg	1,000 ml 4,000 ml	1,000 ml 4,000 ml	1,000 ml 4,000 ml	2 x 1,000 ml 2 x 4,000 ml	3 x 1,000 ml 3 x 4,000 ml

Chickens:
Ascaridia galli and *Heterakis gallinarum:* 1 mg fenbendazole per kg body weight per day (equivalent to 0.005 mlof the veterinary medicinal product) for 5 consecutive days.

Capillaria spp.: 2 mg fenbendazole per kg body weight per day (equivalent to 0.01 mlof the veterinary medicinal product) for 5 consecutive days.

Dose calculation:
The required daily amount of veterinary medicinal product is calculated from the total estimated body weight (kg) of the entire group of chickens to be treated. Please use the following formula:
Treatment of *Ascaridia galli* and *Heterakis gallinarum:*
ml veterinary medicinal product/day = Total estimated body weight (kg) of chicken to be treated x 0.005 ml
Treatment of *Capillaria* spp.
ml veterinary medicinal product/day = Total estimated body weight (kg) of chicken to be treated x 0.01 ml
Examples:

Total body weight of chickens to be treated	**Amount of veterinary medicinal product per day for 1 mg FBZ/ kg (ml/day)**	**Total amount of veterinary medicinal product (ml/for 5 days)**	**Amount of veterinary medicinal product per day for 2 mg FBZ/ kg (ml/day)**	**Total amount of veterinary medicinal product (ml/for 5 days)**
40,000 kg 160,000 kg	200 ml 800 ml	1,000 ml (5x200 ml) 4,000 ml (5x 800 ml)	400 ml 1600 ml	2,000 ml (5x400 ml) 8,000 ml (5x1600 ml)

Follow the instructions in the order described below to prepare the medicated water. Use a sufficiently accurate measuring device, which should be properly cleaned after use.
For each treatment day the medicated water needs to be freshly prepared.
Prepare a predilution of the veterinary medicinal product with an equal amount of water:
1) Select a measuring device that has at least double volume of the calculated daily veterinary medicinal product volume.
2) Pour a volume of water equal to the calculated volume of veterinary medicinal product needed into the measuring device.
3) Shake the veterinary medicinal product well before mixing.
4) Fill up the measuring device containing the water with the calculated volume of the veterinary medicinal product to obtain the predilution.
5) Add the obtained predilution to the water supply system as described below.
For use in medication tank:
Add the entire content of the measuring device (predilution) to the volume of drinking water usually consumed by the animals in between 3 to 24 hours.
Stir until content in the medication tank is visibly homogeneous. The medicated water appears hazy. No further stirring during administration is necessary.

For use in dosing pump:
Add the entire content of the measuring device (predilution) to the unmedicated water in the stock suspension container of the dosing pump. The volume of unmedicated water in the stock suspension container has to be calculated taking as a basis the preset injection rate of the dosing pump and the volume of drinking water usually consumed by the animals in between 3 and 24 hours.
Stir until content in the stock suspension container is visibly homogeneous. The medicated water appears hazy.

At concentrations of up to 5 ml/l stock suspension (1 g fenbendazole/l) no stirring is required.
At concentrations above 5 ml/l stock suspension and up to 75 ml/l stock suspension (15 g fenbendazole/l) and within an administration period of up to 8 hours no stirring of the stock suspension is required. If the administration period exceeds 8 hours, but being no longer than 24 hours, the stock suspension container needs to be equipped with a stirring device.
During treatment all animals must have solely but unrestricted access to the medicated water.
During treatment, after complete consumption of the medicated water, animals must be allowed access to unmedicated drinking water as soon as possible.
Ensure that the total amount of medicated water offered is consumed.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Pigs:
No adverse reactions have been observed at up to ten-fold overdose in pigs.
Chickens:
No adverse reactions have been observed at up to 2.5-fold the maximum recommended dose of 2 mg fenbendazole/ kg body weight in layers and broilers (aged 21 days). A transient mild to moderate reduction in bone marrow cellularity accompanied by a transient reduction in peripheral white blood cell counts and heterophils was observed in 4 out of 12 chickens administered an overdose of 10 mg fenbendazole/kg bodyweight for 21 consecutive days. No adverse reactions have been observed at up to 1.5-fold the maximum recommended dose of 2 mg fenbendazole/ kg body weight in breeders. No detrimental effects on hatchability and chick viability were evident. Higher overdoses have not been tested.

4.11 Withdrawal period(s)

Pigs:
Meat and offal: 4 days.
Chickens:
Meat and offal: 6 days for 1 mg fenbendazole /kg dose;
9 days for 2 mg fenbendazole /kg dose.
Eggs: zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, benzimidazole and related substances – fenbendazole.
ATCvet Code: QP52AC13.

5.1 Pharmacodynamic properties

Fenbendazole is an anthelmintic belonging to the benzimidazole-carbamate group. It acts by interfering with the energy metabolism of the nematode.
Fenbendazole inhibits the polymerisation of tubulin to microtubules. This interferes with essential structural and functional properties of the cells of helminths, such as formation of the cytoskeleton, formation of the mitotic spindle and the uptake and intracellular transport of nutrients and metabolic products. Fenbendazole is effective and has a dose dependent effect on adult and immature stages. Fenbendazole has an ovicidal effect on nematode eggs.

5.2 Pharmacokinetic particulars

After oral administration, fenbendazole is only partially absorbed. Following absorption, fenbendazole is rapidly metabolised in the liver mainly to its sulphoxide (oxfendazole) and further to its sulphone (oxfendazole sulphone). In pigs, oxfendazole is the main component detected in plasma, accounting for about 2/3 of the total AUC (i.e. the sum of the AUC for fenbendazole, oxfendazole and oxfendazole sulphone). In chickens, oxfendazole sulfone is the main component detected in plasma, accounting for about 3/4 of the total AUC (*i.e* the sum of the AUC for fenbendazole, oxfendazole and oxfendazole sulphone). Fenbendazole and its metabolites are distributed throughout the body, reaching highest concentrations in the liver. The elimination of fenbendazole and its metabolites occurs primarily via the faeces and to a small extent in the urine (pigs).

5.3 Environmental properties

Fenbendazole is toxic to fish and other aquatic organisms.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients:

Benzyl alcohol 20 mg Polysorbate 80
Simethicone emulsion 30%

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 6 months.
Shelf life after dilution according to directions: 24 hours.

6.4 Special precautions for storage

Do not freeze.
Protect from frost.

6.5 Nature and composition of immediate packaging

HDPE container with pulp board/aluminium/polyester/MDPE seal closed with child-resistant polypropylene screw cap.

Pack sizes: 1 litre and 4 litres.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.
The veterinary medicinal product should not enter water courses as fenbendazole may be dangerous for fish and other aquatic organisms.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/5051

9. DATE OF FIRST AUTHORISATION

09 December 2011

10. DATE OF REVISION OF THE TEXT

May 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's

competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Approved 04 May 2024