

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
HDPE container (1 and 4 litres presentations)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

200 mg/ml fenbendazole

Excipients:

Benzyl alcohol (E1519) 20 mg

3. PACKAGE SIZE

1 litre

4 litres

4. TARGET SPECIES

Pigs and chickens

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use. Shake well before use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once diluted use within 24 hours.
Once opened, use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.
Protect from frost.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5051

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each ml contains 200 mg fenbendazole and 20 mg benzyl alcohol (E1519).
White to off-white suspension.

3. TARGET SPECIES

Pigs and chickens.

4. INDICATIONS FOR USE

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)

5. CONTRAINDICATIONS

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

6. SPECIAL WARNING(S)

Special warnings:

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.

Special precautions for safe use in the target species:

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 taken 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 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.

Pregnancy and lactation:

Can be used during pregnancy or lactation.

Laying birds:

Can be used in birds in lay.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

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.

Major incompatibilities:

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

7. ADVERSE EVENTS

Pigs, chickens

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first

instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

UK(GB) and UK(NI): Email: adverse.events@vmd.gov.uk

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

IE: HPRA Pharmacovigilance; Website: www.hpra.ie

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

Pigs:

The dose is 2.5 mg fenbendazole per kg body weight per day (equivalent to 0.0125 ml of 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:

$$\text{ml veterinary medicinal product/day} = \text{Total estimated body weight (kg) of pigs to be treated} \times 0.0125 \text{ ml}$$

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	1,000 ml	1,000 ml	1,000 ml	2 x 1,000 ml	3 x 1,000 ml
320,000 kg	4,000 ml	4,000 ml	4,000 ml	2 x 4,000 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 ml of the veterinary medicinal product) for 5 consecutive days.

Capillaria spp.: 2 mg fenbendazole per kg body weight per day (equivalent to 0.01 ml of 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 chicken 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 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 veterinary medicinal of 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 (5 x 200 ml) 4,000 ml (5 x 800 ml)	400 ml 1600 ml	2,000 ml (5x400 ml) 8,000 ml (5x1600 ml)

9. ADVICE ON CORRECT ADMINISTRATION

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.

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 hour also 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, the animals must be allowed access to unmedicated drinking water as soon as possible.

Ensure that the total amount of medicated water offered is consumed.

10. WITHDRAWAL PERIODS

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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not freeze. Protect from frost.

Do not use this veterinary medicinal product after the expiry date which is stated on the label Exp.

The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 6 months.

Shelf life after dilution according to directions: 24 hours.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
This 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 product should be disposed of in accordance with local requirements. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 01708/5051

Pack sizes: Container of 1 litre and 4 litres.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

Manufacturer responsible for batch release:

Intervet Productions S.A.
Rue de Lyons
27460 Igoville
France

Contact details to report suspected adverse reactions:
MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

17. OTHER INFORMATION

Fenbendazole has an ovicidal effect on nematode eggs.
 POM-V Veterinary medicinal product subject to prescription

For animal treatment only.

Approved 04 May 2024

A handwritten signature in black ink, appearing to read "A. Hunter.", is positioned below the approval date.