

ANNEX I
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

1 ml contains:

Active substance:

Fenbendazole 200 mg

Excipient:

Benzyl alcohol (E1519) 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

None.

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.

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 taken by the person administering the veterinary medicinal product to animals

This veterinary medicinal product may be toxic to humans after ingestion. 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.

Other precautions

The veterinary medicinal product should not be allowed to enter surface waters as it has harmful effects on aquatic organisms.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy, lactation or lay.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

In drinking water use.

To ensure administration of the correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be 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 Panacur AquaSol). 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 product is calculated from the total estimated body weight (kg) of the entire group of pigs to be treated. Please use the following formula:

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

Examples:

Total body weight of pigs to be treated	Day 1 amount of product	Day 2 amount of product	Day 3 amount of 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 Panacur AquaSol) for 5 consecutive days.

Capillaria spp.: 2 mg fenbendazole per kg body weight per day (equivalent to 0.01 ml Panacur AquaSol) for 5 consecutive days.

Dose calculation:

The required daily amount of 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*:

$$\text{ml product/day} = \text{Total estimated body weight (kg) of chicken to be treated} \times 0.005 \text{ ml}$$

Treatment of *Capillaria* spp.

$$\text{ml product/day} = \text{Total estimated body weight (kg) of chicken to be treated} \times 0.01 \text{ ml}$$

Examples:

Total body weight of chickens to be treated	Amount of product per day for 1 mg FBZ/ kg (ml/day)	Total amount of product (ml/for 5 days)	Amount of product per day for 2 mg FBZ/ kg (ml/day)	Total amount of product (ml/for 5 days)
40,000 kg	200 ml	1,000 ml (5x200 ml)	400 ml	2,000 ml (5x400 ml)
160,000 kg	800 ml	4,000 ml (5x 800 ml)	1600 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 product volume.
- 2) Pour a volume of water equal to the calculated volume of product needed into the measuring device.
- 3) Shake the product well before mixing.
- 4) Fill up the measuring device containing the water with the calculated volume of the 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).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Simethicone emulsion 30 %
Benzyl alcohol (E1519)
Purified water

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.

The 4 litre container is provided with a separate dispenser made of low density polyethylene and polypropylene.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Panacur AquaSol should not enter water courses as this may be dangerous for fish and other aquatic organisms

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands
Tel.: +31 485 587600
Fax: +31 485 577333

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/135/002
EU/2/11/135/003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9 December 2011
Date of last renewal: 26 August 2016

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

- A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substance in Panacur AquaSol is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Fenbendazole	Sum of extractable residues which may be oxidised to oxfendazole sulphone	All food-producing species except fin fish	50 µg/kg 50 µg/kg 500 µg/kg 50 µg/kg 10 µg/kg 1300 µg/kg	Muscle Fat Liver Kidney Milk Eggs	For porcine and poultry species the fat MRL relates to 'skin and fat in natural proportions'.	Antiparasitic agents/Agents against endoparasites

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE 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 for pigs and chickens
Fenbendazole

2. STATEMENT OF ACTIVE SUBSTANCES

200 mg/ml fenbendazole

3. PHARMACEUTICAL FORM

Suspension for use in drinking water

4. PACKAGE SIZE

1 l
4 l

5. TARGET SPECIES

Pigs and chickens

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Suspension for use in drinking water
Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

Once diluted use within 24 hours.

Once opened, use by...

11. SPECIAL STORAGE CONDITIONS

Do not freeze. Protect from frost.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/135/002
EU/2/11/135/003

17. MANUFACTURER'S BATCH NUMBER

Lot

B. PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

The veterinary medicinal product is a white to off-white suspension for use in drinking water containing 200 mg/ml of fenbendazole and 20 mg/ml of benzyl alcohol (E1519).

4. INDICATION(S)

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

None.

6. ADVERSE REACTIONS

None known.

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 inform your veterinary surgeon.

7. TARGET SPECIES

Pigs and chickens.

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

In drinking water use.

To ensure administration of the correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Pigs:

The dose is 2.5 mg fenbendazole per kg body weight per day (equivalent to 0.0125 ml Panacur AquaSol). 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 product is calculated from the total estimated body weight (kg) of the entire group of pigs to be treated. Please use the following formula:

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

Examples:

Total body weight of pigs to be treated	Day 1 amount of product	Day 2 amount of product	Day 3 amount of 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 Panacur AquaSol) for 5 consecutive days.

Capillaria spp.: 2 mg fenbendazole per kg body weight per day (equivalent to 0.01 ml Panacur AquaSol) for 5 consecutive days.

Dose calculation:

The required daily amount of 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*:

$$\text{ml product/day} = \text{Total estimated body weight (kg) of chicken to be treated} \times 0.005 \text{ ml}$$

Treatment of *Capillaria* spp.

$$\text{ml product/day} = \text{Total estimated body weight (kg) of chicken to be treated} \times 0.01 \text{ ml}$$

Examples:

Total body weight of chickens to be treated	amount of product per day for 1 mg FBZ/ kg (ml/day)	Total amount of product (ml/for 5 days)	amount of product per day for 2 mg FBZ/ kg (ml/day)	Total amount of product (ml/ for 5 days)
40,000 kg	200 ml	1,000 ml (5 x 200 ml)	400 ml	2,000 ml (5x400 ml)
160,000 kg	800 ml	4,000 ml (5 x 800 ml)	1600 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 product volume.
- 2) Pour a volume of water equal to the calculated volume of product needed into the measuring device.
- 3) Shake the product well before mixing.
- 4) Fill up the measuring device containing the water with the calculated volume of the 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 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.

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.

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

Shelf life after dilution according to directions: 24 hours.

12. SPECIAL WARNINGS

Special precautions for use in animals:

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

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

This product may be toxic to humans after ingestion. 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.

Pregnancy, lactation and lay:

Can be used during pregnancy and lactation or lay.

Incompatibilities:

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Panacur AquaSol should not enter water courses as this may be dangerous for fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

15. OTHER INFORMATION

Fenbendazole has an ovicidal effect on nematode eggs.

Container of 1 litre and 4 litres. The 4 litres container is provided with a separate dispenser.

Not all pack sizes may be marketed.