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

Each ml contains:

Active substance:

Fenbendazole 200 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	20 mg
Polysorbate 80	
Simethicone emulsion 30%	
Water, purified	

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

3. CLINICAL INFORMATION

3.1 Target species

Pigs and chickens

3.2 Indications for use for each 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)

3.3 Contraindications

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

3.4 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 veterinary medicinal 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/group.

3.5 Special precautions for use

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 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.

3.6 Adverse events

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy or lactation.

Laying birds:
Can be used in birds in lay.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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 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:

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	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 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 veterinary medicinal 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 (5x800 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 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.

<u>For use in medication tank:</u>
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.

<u>For use in dosing pump:</u>
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC13.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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).

Environmental properties

Fenbendazole is toxic to fish and other aquatic organisms.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

Do not freeze.
Protect from frost.

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

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

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09 December 2011

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD month YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

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

2. STATEMENT OF ACTIVE SUBSTANCES

200 mg/ml fenbendazole

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

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/11/135/002 (1L)
EU/2/11/135/003 (4L)

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

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 warnings

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 veterinary medicinal 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/group.

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 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.

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: {national system details}.

8. Dosage for each species, routes 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:

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	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 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**	**Total amount of veterinary medicinal product (ml/for 5 days)**	**Amount of veterinary medicinal product per day for 2 mg**	**Total amount of veterinary medicinal product (ml/for 5 days)**

	FBZ/kg (ml/day)		**FBZ/kg (ml/day)**	
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.

<u>For use in medication tank:</u>
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.

<u>For use in dosing pump:</u>
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 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 after 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 or household waste.

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. 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

EU/2/11/135/002 (1L)
EU/2/11/135/003 (4L)

Pack sizes: Container of 1 litre and 4 litres.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD month YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

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

België/Belgique/Belgien
Tél/Tel: + 32 (0)2 370 94 01

Република България
Тел: + 359 28193749

Česká republika
Tel: + 420 233 010 242

Danmark
Tlf: + 45 44 82 42 00

Deutschland
Tel: + 49 (0)8945614100

Eesti
Tel: + 37052196111

Ελλάδα
Τηλ: + 30 210 989 7452

España
Tel: + 34 923 19 03 45

France
Tél: + 33 (0)241228383

Hrvatska
Tel: + 385 1 6611339

Ireland
Tel: + 353 (0) 1 2970220

Ísland
Sími: + 354 535 7000

Italia
Tel: + 39 02 516861

Κύπρος
Τηλ: + 30 210 989 7452

Latvija
Tel: + 37052196111

Lietuva
Tel: + 37052196111

Luxembourg/Luxemburg
Tél/Tel: + 32 (0)2 370 94 01

Magyarország
Tel.: + 36 1 439 4597

Malta
Tel: + 39 02 516861

Nederland
Tel: + 32 (0)2 370 94 01

Norge
Tlf: + 47 55 54 37 35

Österreich
Tel: + 43 (1) 256 87 87

Polska
Tel.: + 48 22 18 32 200

Portugal
Tel: + 351 214 465 700

România
Tel: + 40 21 311 83 11

Slovenija
Tel: + 385 1 6611339

Slovenská republika
Tel: + 420 233 010 242

Suomi/Finland
Puh/Tel: + 358 10 2310 750

Sverige
Tel: + 46 (0)8 522 216 60

United Kingdom (Northern Ireland)
Tel: + 353 (0) 1 2970220

Manufacturer responsible for batch release:

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

17. Other information

Fenbendazole has an ovicidal effect on nematode eggs.