

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Fungitraxx 10 mg/ml oral solution for ornamental birds

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each ml contains:

### **Active substance:**

Itraconazole 10 mg.

For the full list of excipients, see section 6.1.

## **3. PHARMACEUTICAL FORM**

Oral solution.

Yellow to slightly amber, clear solution.

## **4. CLINICAL PARTICULARS**

### **4.1 Target species**

Ornamental birds, particularly:

Psittaciformes (specifically cockatoos and true parrots: parakeets; budgerigars)

Falconiformes (falcons)

Accipitriformes (hawks)

Strigiformes (owls)

Anseriformes (specifically swans)

### **4.2 Indications for use, specifying the target species**

Psittaciformes, Falconiformes, Accipitriformes, Strigiformes, and Anseriformes:

For the treatment of aspergillosis.

Psittaciformes (only):

Also for the treatment of candidiasis.

### **4.3 Contraindications**

Do not use in birds intended for human consumption.

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

### **4.4 Special warnings for each target species**

None.

## 4.5 Special precautions for use

### Special precautions for use in animals

Itraconazole is generally not well tolerated by African Grey Parrots and therefore the product should only be used with care in this species and if no alternative treatment is available and with the lowest recommended dose for the whole of the recommended treatment period.

Other Psittaciformes also appear less tolerant to itraconazole than other birds. Therefore if suspected adverse reactions such as emesis, anorexia or weight loss occur, the dose should be lowered, or treatment with the medicinal product should be discontinued.

Where there is more than one bird in the home/cage, all infected and treated birds should be separated from other birds.

In accordance with good animal husbandry, the cleaning and disinfection of the infected birds' environment with an appropriate antifungal product should be recommended. An appropriate rate of air renewal in the environment of the treated bird(s) is also important.

Frequent and repeated use of antifungals from the same class may increase the risk of development of resistance to that class of antifungals.

The prevalence of such acquired resistance may vary geographically and over time for specific species, and therefore local information on antifungal/azole resistance is desirable, particularly when treating severe infections.

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

Wash hands and exposed skin after use.

In case of accidental contact with the eyes, rinse thoroughly with water.

In case of accidental ingestion, rinse the mouth with water and seek medical advice immediately and show the package leaflet or the label to the physician.

Some fungal infections of birds can be zoonotic diseases and infect humans. Because of the risk of transmission of aspergillosis to people, personal protective equipment consisting of latex gloves and a mask should therefore be worn when handling infected birds or when cleaning the syringe. If suspected lesions (such as the occurrence of cutaneous nodules or erythematous papules, respiratory symptoms such as coughing and wheezing) occur in humans, consult a physician.

## 4.6 Adverse reactions (frequency and seriousness)

Itraconazole generally has a narrow margin of safety in birds.

Emesis, anorexia and weight loss have commonly been observed in treated birds, however, these adverse reactions are usually mild and dose related. If emesis, anorexia or weight loss occurs, then in the first instance it is advisable to lower the dose (see section 4.5) or treatment with the veterinary medicinal product should be discontinued.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

#### **4.7 Use during pregnancy, lactation or lay**

Do not use in birds in lay and within 4 weeks before the start of the laying period.

Laboratory studies in rats have shown evidence of dose-related teratogenic, foetotoxic and maternotoxic effects at high dosages (40 and 160 mg/kg bodyweight administered daily for 10 days during their gestational period).

#### **4.8 Interaction with other medicinal products and other forms of interaction**

No information is available on the safety and efficacy of this veterinary medicinal product when used in the target species with any other veterinary medicinal product. Therefore co-administration of this product with other veterinary medicinal products should be avoided. The information below is indicative of the known interactions in humans, and in animals other than birds.

In humans it is known that itraconazole can inhibit the metabolism of medicinal products that are substrates for cytochrome 3A isoenzymes, for example, chloramphenicol, ivermectin or methylprednisolone. Although the relevance of this information for the target species is unknown, it would be prudent to avoid the concurrent use of such substances with this product because an increase and/or a prolongation of their pharmacological effects, including side effects, may occur. The concomitant use of erythromycin can result in an increased plasma concentration of itraconazole.

Laboratory animal studies have shown that itraconazole used concomitantly with amphotericin B may be antagonistic against *Aspergillus* spp. or *Candida* spp.; the clinical importance of these findings is unclear.

#### **4.9 Amounts to be administered and administration route**

Oral use.

##### Dose and treatment schedule:

Aspergillosis: 5 to 10 mg (0.5 ml to 1 ml) itraconazole per kg bodyweight per day for 8 weeks. For the treatment of African Grey Parrots (see section 4.5) use no more than 5 mg (0.5 ml) itraconazole per kg bodyweight per day. If clinical signs show that the product is not well tolerated, then the treatment should be stopped.

In cases where, 8 weeks after the start of treatment, clinical signs are still present, or endoscopy indicates a fungal presence remains, the whole 8 weeks course of treatment should be repeated (using the same dose regimen).

Candidiasis (Psittaciformes only):

10 mg (1 ml) itraconazole per kg bodyweight per day for 14 days.  
For the treatment of African Grey Parrots use no more than 5 mg (0.5 ml) itraconazole per kg bodyweight per day for 14 days (see section 4.5).

##### Method of administration:

To ensure the correct dose, and to avoid underdosing and overdosing, the bodyweight(s) of the bird(s) to be treated should be determined as accurately as possible.

The best method of administration of the oral solution is directly into the bird's mouth. However, if direct oral administration is not feasible (for example, for raptors) the medicinal product can be administered with the bird's food. (For example, for raptors a 'spiked' chick is generally used.) If the product has to be administered with the bird's food, it should then be offered immediately to the bird(s), and discarded within 1 hour if it has not been consumed by then.

The 1 ml oral syringe has graduations for 0.05 ml solution (= 0.5 mg itraconazole).  
The 5 ml oral syringe has graduations for 0.2 ml solution (= 2 mg itraconazole).

Remove the screw cap on the bottle. Using the oral syringe provided, place the syringe nozzle into the opening of the bottle and withdraw the necessary volume. Replace the screw cap after use.

Slowly and gently administer the oral solution into the mouth of the bird, allowing the bird to swallow it.

After dosing, the syringe should be washed with hot water and dried.

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

No information on overdose is currently available in the target species (see section 4.6.).

#### **4.11 Withdrawal period(s)**

Not applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Antimycotics for systemic use, triazole derivatives.  
ATCvet code: QJ02AC02.

#### **5.1 Pharmacodynamic properties**

The mode of action of itraconazole is based on its highly selective binding ability for fungal cytochrome P-450 isoenzymes. Itraconazole inhibits the synthesis of ergosterol. It also affects membrane-bound enzyme function and membrane permeability, and as this effect is irreversible it results in structural degeneration of the fungus.

The minimum inhibitory concentrations of itraconazole for different *Aspergillus* isolates in birds in Europe varies between 0.25 and >16 µg/ml.

Data were limited on the minimum inhibitory concentrations for different *Candida* isolates.

Resistance to azole antifungals is most commonly exhibited by modification of the *cyp51A* gene which encodes for the target enzyme 14- $\alpha$ -sterol demethylase. Cross-resistance amongst members of the azole class of drugs has been observed within *Candida* species, although resistance to one member of the class does not necessarily confer resistance to other azoles. Some resistant isolates have been identified from avian *Aspergillus fumigatus*.

#### **5.2 Pharmacokinetic particulars**

In birds, itraconazole plasma concentrations vary with the type of bird. The different target species consume different types of food and exhibit differing metabolism. One metabolite, hydroxyitraconazole, has the same antifungal activity as the parent drug.

Itraconazole elimination may be a saturable process. Because of its long half-life, itraconazole does not reach steady state plasma levels for at least 6 days after the start of treatment.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Hydroxypropylbetadex  
Caramel flavour  
Propylene glycol  
Hydrochloric acid (for pH adjustment)  
Sodium hydroxide (for pH adjustment)  
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: 18 months.  
Shelf life after first opening the immediate packaging: 28 days.

## **6.4 Special precautions for storage**

Do not store above 25 °C.  
Do not refrigerate or freeze.  
Keep the bottle in the outer carton in order to protect from light.  
Keep the bottle tightly closed.

## **6.5 Nature and composition of immediate packaging**

Cardboard box containing an amber glass (type III) bottle with a tamper-evident polypropylene screw cap and LDPE insert. A graduated polypropylene oral syringe is also included.

Box containing 1 bottle of 10 ml with one 1 ml oral syringe.  
Box containing 1 bottle of 50 ml with one 5 ml oral syringe.  
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 product should be disposed of in accordance with local requirements.

## **7. MARKETING AUTHORISATION HOLDER**

Avimedical B.V.  
Abbinkdijk 1  
7255 LX Hengelo (Gld)  
THE NETHERLANDS

## **8. MARKETING AUTHORISATION NUMBER(S)**

EU/2/13/160/001–002

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

DD/MM/YYYY

## **10 DATE OF REVISION OF THE TEXT**

<{MM/YYYY}>

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

Floris Veterinaire Produkten B.V.  
Kempenlandstraat 33  
5262 GK Vught  
THE NETHERLANDS

**B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

Veterinary medicinal product subject to prescription.

**C. STATEMENT OF THE MRLs**

Not applicable.

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Outer carton**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Fungitraxx 10 mg/ml oral solution for ornamental birds  
itraconazole

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Itraconazole 10 mg/ml

**3. PHARMACEUTICAL FORM**

Oral solution.

**4. PACKAGE SIZE**

10 ml including oral syringe  
50 ml including oral syringe

**5. TARGET SPECIES**

Ornamental birds

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.  
Oral use.

**8. WITHDRAWAL PERIOD**

**9. SPECIAL WARNING(S), IF NECESSARY**

Do not use in birds intended for human consumption.  
Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

Once opened, use within 28 days.

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 25 °C.

Do not refrigerate or freeze.

Keep the bottle in the outer carton in order to protect from light.

**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**

Avimedical B.V.  
Abbinkdijk 1  
7255 LX Hengelo (Gld)  
THE NETHERLANDS.

**16. MARKETING AUTHORISATION NUMBER(S)**

EU/2/13/160001  
EU/2/13/160/002

**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Bottle (10 ml and 50 ml)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Fungitraxx 10 mg/ml oral solution  
itraconazole

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Itraconazole 10 mg/ml

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

10 ml  
50 ml

**4. ROUTE(S) OF ADMINISTRATION**

**5. WITHDRAWAL PERIOD**

**6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {month/year}

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET FOR:  
Fungitraxx 10 mg/ml oral solution for ornamental birds**

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

Marketing authorisation holder:

Avimedical B.V.  
Abbinkdijk 1  
7255 LX Hengelo (Gld)  
THE NETHERLANDS

Manufacturer responsible for batch release:

Floris Veterinaire Produkten B.V.  
Kempenlandstraat 33  
5262 GK Vught  
THE NETHERLANDS

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Fungitraxx 10 mg/ml oral solution for ornamental birds  
itraconazole

**3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT(S)**

**Active substance:**

Itraconazole 10 mg/ml

**Description:**

Yellow to slightly amber, clear solution.

**4. INDICATION(S)**

Psittaciformes, Falconiformes, Accipitriformes, Strigiformes, and Anseriformes:

For the treatment of aspergillosis.

Psittaciformes (only):

Also for the treatment of candidiasis.

**5. CONTRAINDICATIONS**

Do not use in birds intended for human consumption.

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



## 6. ADVERSE REACTIONS

Itraconazole generally has a narrow margin of safety in birds.

Vomiting, loss of appetite and loss of weight have commonly been observed in treated birds, however, these adverse reactions are usually mild and dose related. If vomiting, loss of appetite or loss of weight occurs, then in the first instance it is advisable to lower the dose (see section “Special warnings”) or treatment with the veterinary medicine should be discontinued.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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

Ornamental birds, particularly:

Psittaciformes (specifically cockatoos and true parrots: parakeets; budgerigars)

Falconiformes (falcons)

Accipitriformes (hawks)

Strigiformes (owls)

Anseriformes (specifically swans)

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

*Administration route:*

Oral use.

*Amounts to be administered:*

Aspergillosis: 5 to 10 mg (0.5 ml to 1 ml) itraconazole per kg bodyweight per day for 8 weeks.  
For the treatment of African Grey Parrots (see section “Special warnings”) use no more than 5 mg (0.5 ml) itraconazole per kg bodyweight per day. If clinical signs show that the product is not well tolerated, then the treatment should be stopped.

In cases where, 8 weeks after the start of treatment, clinical signs are still present, or endoscopy indicates a fungal presence remains, the whole 8 weeks course of treatment should be repeated (using the same dosage regimen).

Candidiasis (Psittaciformes only):

10 mg (1 ml) itraconazole per kg bodyweight per day for 14 days.  
For the treatment of African Grey Parrots use no more than 5 mg (0.5 ml) itraconazole per kg bodyweight per day for 14 days (see section “Special warnings”).

## 9. ADVICE ON CORRECT ADMINISTRATION

Do not use the medicine if you notice visible signs of deterioration.

To ensure the correct dose, and to avoid underdosing and overdosing, the bodyweight(s) of the bird(s) to be treated should be determined as accurately as possible. Your veterinarian will decide the correct dose for your bird(s).

The best method of administration of the oral solution is directly into the bird's mouth. However, if direct oral administration is not feasible (for example, for raptors) the medicinal product can be administered with the bird's food. (For example, for raptors a 'spiked' chick is generally used.) If the product has to be administered with the bird's food, it should then be offered immediately to the bird(s), and discarded within 1 hour if it has not been consumed by then.

The 1 ml oral syringe has graduations for 0.05 ml solution (= 0.5 mg itraconazole).  
The 5 ml oral syringe has graduations for 0.2 ml solution (= 2 mg itraconazole).

Remove the screw cap on the bottle. Using the oral syringe provided, place the syringe nozzle into the opening of the bottle and withdraw the necessary volume. Replace the screw cap after use.

Slowly and gently administer the oral solution into the mouth of the bird, allowing the bird to swallow it.

After dosing, the syringe should be washed with hot water and dried.

## **10. WITHDRAWAL PERIOD**

Not applicable.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Do not store above 25 °C.

Do not refrigerate or freeze.

Keep the bottle in the outer carton in order to protect from light.

Keep the bottle tightly closed.

Do not use this veterinary medicine after the expiry date which is stated on the label and carton.

Shelf life after first opening the bottle: 28 days.

## **12. SPECIAL WARNING(S)**

Special warnings for each target species:

None.

Special precautions for use in animals:

Itraconazole is generally not well tolerated by African Grey Parrots and therefore the product should only be used with care in this species and if no alternative treatment is available and with the lowest recommended dose for the whole of the recommended treatment period.

Other Psittaciformes also appear less tolerant to itraconazole than other birds. Therefore if suspected adverse reactions related to this medicine, such as vomiting, loss of appetite or weight loss occur, the dose should be lowered, or treatment with the medicinal product should be discontinued.

Where there is more than one bird in the home/cage, all infected and treated birds should be separated from other birds.

In accordance with good animal husbandry, the cleaning and disinfection of the infected birds' environment with an appropriate antifungal product is recommended. An appropriate rate of air renewal in the environment of the treated birds is also important.

Frequent and repeated use of antifungals from the same class may increase the risk of development of resistance to that class of antifungals.

The prevalence of such acquired resistance may vary geographically and over time for specific species, and therefore local information on antifungal/azole resistance is desirable, particularly when treating severe infections.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:  
Wash hands and exposed skin after use.

In case of accidental contact with the eyes, rinse thoroughly with water.

In case of accidental ingestion, rinse the mouth with water and seek medical advice immediately and show the package leaflet or the label to the physician.

Some fungal infections of birds can be zoonotic diseases and infect humans. Because of the risk of transmission of aspergillosis to people, protective personal equipment consisting of latex gloves and a mask should therefore be worn when handling infected birds or when cleaning the syringe. If suspected lesions (such as the occurrence of cutaneous nodules or erythematous papules, respiratory symptoms such as coughing and wheezing) occur in humans, consult a physician.

Lay:

Do not use in birds in lay and within 4 weeks before the start of the laying period.

Laboratory studies in pregnant rats administered high dosages (40 and 160 mg/kg bodyweight daily for 10 days) have shown evidence of dose-related harmful effects to the pregnant rat and to the embryo/foetus.

Interaction with other medicinal products and other forms of interaction:

No information is available on the safety and efficacy of this veterinary medicinal product when used in the target species with any other veterinary medicinal product. Co-administration of this product with other veterinary medicinal products should therefore be avoided. The information in the paragraph below is a summary of the known interactions between itraconazole and other medicinal products in humans, and in animals other than birds.

In humans it is known that itraconazole can inhibit the metabolism of medicinal products that are substrates for cytochrome 3A isoenzymes, for example, chloramphenicol, ivermectin or methylprednisolone. Although the relevance of this information for the target species (ornamental birds) is unknown, it is wise to avoid the use of such substances together with this product because an increase and/or a prolongation of their pharmacological effects, including side effects, may occur.

The concomitant use of the antibiotic erythromycin can result in an increased plasma concentration of itraconazole in the blood of the bird, which may result in increased adverse effects.

Laboratory animal studies have shown that when itraconazole is used together with amphotericin B it may be antagonistic against *Aspergillus* spp. or *Candida* spp.; the clinical importance of these findings is unclear.

Overdose (symptoms, emergency procedures, antidotes):

No information on overdose is currently available in the target species. (See section “Adverse reactions”.)

Major 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 or household waste.

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

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

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

**15. OTHER INFORMATION**

Pharmacotherapeutic group: Antimycotics for systemic use, triazole derivatives.  
ATCvet code: QJ02AC02.

**Pharmacodynamic properties**

The mode of action of itraconazole is based on its highly selective binding ability for fungal cytochrome P-450 iso-enzymes. Itraconazole inhibits the synthesis of ergosterol. It also affects membrane-bound enzyme function and membrane permeability, and as this effect is irreversible it results in structural degeneration of the fungus.

The minimum inhibitory concentrations of itraconazole for different *Aspergillus* isolates in birds in Europe varies between 0.25 and >16 µg/ml.

Data were limited on the minimum inhibitory concentrations for different *Candida* isolates.

Resistance to azole antifungals is most commonly exhibited by modification of the *cyp51A* gene which encodes for the target enzyme 14- $\alpha$ -sterol demethylase. Cross-resistance amongst members of the azole class of drugs has been observed within *Candida* species although resistance to one member of the class does not necessarily confer resistance to other azoles. Some resistant isolates have been identified from avian *Aspergillus fumigatus*.

**Pharmacokinetic particulars**

In birds, itraconazole plasma concentrations vary with the type of bird. The different target species consume different types of food and exhibit differing metabolism. One metabolite, hydroxyitraconazole, has the same antifungal activity as the parent drug.

Itraconazole elimination may be a saturable process. Because of its long half-life, itraconazole does not reach steady state plasma levels for at least 6 days after the start of treatment.

**Package sizes**

Cardboard box containing an amber glass (type III) bottle with a tamper-evident polypropylene screw cap and LDPE insert. A graduated polypropylene oral syringe is also included.

Box containing 1 bottle of 10 ml with one 1 ml oral syringe.

Box containing 1 bottle of 50 ml with one 5 ml oral syringe.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

### **The Netherlands**

Fendigo SA

Av Herrmann Debrouxlaan 17 B

1160 Oudergem- Brussels

Tel.: 0032-27344899

Topet Farma B.V.

Dr. Grashuisstraat 8

7021 CL Zelhem

Tel.: 0031-314 622 607

### **Belgium**

Fendigo SA

Av. Herrmann-Debrouxlaan 17 B

1160 Oudergem- Brussels

Tel.: 0032-27344899

### **Germany**

Dechra Veterinary Products/Albrecht GmbH

Veterinär-medizinische Erzeugnisse

Hauptstr. 6-8 88326 Aulendorf

Tel.: 0049-7525205-71

### **Austria**

Dechra Veterinary Products GmbH-Austria

Hintere Achmühlerstraße 1A

6850 Dornbirn

Tel.: 0043-557240242-55

### **United Kingdom**

Petlife International Ltd.

Unit 2, 2 Cavendish Rd

Bury Saint Edmunds IP33 3TE

Tel.: 0044-1284761131

### **Ireland**

Duggan Veterinary Supplies Ltd.

Holycross

Thurles, Co. Tipperary

Tel.: 00353-50443169

### **Spain**

Mascotasana s.a.

Poima 26

Poligono Industrial Can Valero 07011  
Palma de Mallorca  
Tel.: 0034- 902502059

**Poland**

Vet-Animal  
ul. Lubichowska 126  
83-200 Starogard Gdański  
Tel.: 0048-583523849

**France/ Luxembourg/ Portugal/ Italy/ Sweden/ Finland/ Czech Republic/ Slovakia/ Hungary/ Bulgaria/  
Romania/ Croatia/ Slovenia/ Republic of Cyprus/ Denmark/ Estonia/ Latvia/ Lithuania/ Malta:**

Topet Farma B.V.  
Dr. Grashuisstraat 8  
7021 CL Zelhem  
The Netherlands  
Tel.: 0031-314 622 607