ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Itrafungol 10 mg/ml Oral Solution
Itrafungol vet 10 mg/ml Oral Solution (DK, FI, NO, SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains :

Active substance:

Itraconazole 10 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Caramel (E150)	0.2 mg
Propylene glycol (E1520)	103.6 mg
Sorbitol 70% Non-crystallising Solution	245.1 mg
Hydroxypropyl-b-cyclodextrin	
Concentrated hydrochloric acid	
Sodium hydroxide	
Sodium saccharin	
Cherry flavour	
Purified water	

Yellow to slightly amber, clear solution.

3. CLINICAL INFORMATION

3.1 Target Species

Cats.

3.2 Indications for use, for each target species

Treatment of dermatophytosis caused by *Microsporum canis*.

3.3 Contraindications

Do not use in cats with hypersensitivity to itraconazole or one of the other ingredients.
Do not use in cats with impaired liver or kidney function.
For use in pregnant and lactating queens: see section 3.7

3.4 Special warnings

Some cases of feline dermatophytosis can be difficult to cure, especially in catteries. Cats treated with itraconazole can still infect other cats with *M. canis* as long as they are not mycologically cured. It is therefore advised to minimise the risk of re-infection or spread of infection by keeping healthy animals (including dogs as they can also be infected by *M. canis*) separate from cats that are being treated. Cleaning and disinfection of the environment with appropriate fungicidal products is highly recommended – especially in case of group problems.

When clipping the hair of infected cats, the advice of the veterinarian should be sought first.

Clipping of the hair coat is considered useful because it removes infected hairs, stimulates new hair growth and hastens recovery. It is strongly recommended that clipping is performed by a veterinarian. In cases with limited lesions, hair clipping can be limited to the lesions only, whereas in cats with generalized dermatophytosis it is recommended to clip the entire hair coat. Care should be taken not to cause trauma to the underlying skin during clipping. It is recommended that disposable, protective clothing and gloves are worn during the clipping of the affected animals. The clipping of the hair should be performed in a well ventilated room which can be disinfected after clipping. The hairs should be disposed of appropriately and all instruments, clippers etc. should be disinfected.

Treatment of dermatophytosis should not be limited to treatment of the infected animal(s). It should also include disinfection of the environment with appropriate fungicidal products, since *M. canis* spores can survive in the environment for up to 18 months. Other measures such as frequent vacuuming, disinfection of grooming equipment and removal of all potentially contaminated material that cannot be disinfected will minimize the risk of re-infection or spread of infection. Disinfection and vacuuming should be continued for an extended period after the cat is clinically cured, but vacuuming should be limited to surfaces, which may not be cleaned with a damp cloth. All other surfaces should be cleaned with a damp cloth. Any cloth used for cleaning should be washed and disinfected or disposed of and the used vacuum cleaner bag should be disposed of.

Measures to prevent introduction of *M.canis* into groups of cats may include isolation of new cats, isolation of cats returning from shows or breeding, exclusion of visitors and periodic monitoring by Wood's lamp or by culturing for *M.canis*.

In refractory cases the possibility of an underlying disease should be considered.

Frequent and repeated use of an antimycotic may result in the induction of resistance to antimycotics of the same class.

Refer to section 3.5 for Operator warnings.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Cats suffering from dermatophytosis, but also in poor general condition and/or suffering from additional diseases or impaired immunological response should be monitored closely during treatment. Because of their condition, this category of animals may be more sensitive to the development of adverse effects. In case of a serious adverse effect, treatment should be interrupted and supportive care therapy (fluid therapy) should be initiated if necessary. If clinical signs suggestive of liver dysfunction develop, treatment should be discontinued immediately. It is very important to monitor liver enzymes in animals showing signs of liver dysfunction.

In humans, itraconazole has been associated with heart failure due to a negative inotropic effect. Cats suffering from heart diseases should be carefully monitored and the treatment should be withdrawn if the clinical signs deteriorate.

Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

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

If a suspected lesion occurs on a human, consult a physician, since *M.canis* dermatophytosis is a zoonotic disease. Therefore, wear latex gloves when clipping hair of infected cats, when handling the animal during treatment or when cleaning the syringe.

Wash hands and exposed skin after use. In case of accidental contact with eyes, rinse thoroughly with water. In case of pain or irritation, seek medical advice immediately and show the package leaflet or the label to the physician. In case of accidental ingestion, rinse mouth with water.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Common (1 to 10 animals / 100 animals treated):	Vomiting, Diarrhoea, Increased salivation Anorexia, Depression, Apathy[1]
Rare (1 to 10 animals / 10,000 animals treated):	Elevated liver enzymes[2,3,4]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Weight loss Elevated total bilirubin[3,4] (may be associated with icterus)

[1] These effects are usually mild and transient.
[2] Transient.
[3] If clinical signs suggestive of liver dysfunction develop, treatment should be discontinued immediately.
[4] Sometimes fatal.

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 its local representative or the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not use in pregnant or lactating queens. Malformations and foetal resorptions were seen in overdose studies in laboratory animals.

3.8 Interaction with other medicinal products and other forms of interactions

Vomiting, hepatic and renal disorders were seen after concomitant treatment of Itrafungol and cefovecin. Symptoms like motor incoordination, faecal retention and dehydration are observed when tolfenamic acid and Itrafungol are given simultaneously. Co-administration of the product and these drugs, in absence of data in cats, should be avoided.

In human medicine, interactions between itraconazole and certain other drugs have been described, resulting from interactions with cytochrome P450 3A4 (CYP3A4) and P-glycoproteins (PgP). This may result in increased plasma concentrations of e.g. oral midazolam, cyclosporin, digoxin, chloramphenicol, ivermectin, or methylprednisolone. The increased plasma levels can prolong the duration of effects as well as side effects. Itraconazole may also increase the serum level of oral antidiabetic agents, which may result in hypoglycaemia.
On the other hand, some drugs, e.g. barbiturates or phenytoin can increase the rate of metabolism of itraconazole, resulting in a decreased bioavailability, hence a decreased efficacy. As itraconazole

requires an acidic environment for maximal absorption, antacids cause a marked reduction in absorption. Concomitant use of erythromycin can increase the plasma concentration of itraconazole. Interactions in humans between itraconazole and calcium antagonists have also been reported. These drugs might have additive negative inotropic effects to the heart.

It is not known to what extent these interactions are relevant for cats, but in the absence of data, co-administration of the product and these drugs should be avoided.

3.9 Administration routes and dosage

Oral use.
The solution is administered orally directly into the mouth by means of a dosing syringe. The daily dosage is 5 mg/kg or 0.5 ml/kg/day.
The dosage regime is 0.5 ml/kg/day for 3 alternate periods of 7 consecutive days, each time with 7 days without treatment in between.

7 Days	7 Days	7 Days	7 Days	7 Days
Treatment	No treatment	Treatment	No treatment	Treatment

The dosing syringe shows graduations per 100 gram of body weight. Fill the syringe by pulling the plunger until it reaches the graduation corresponding to the correct body weight of the cat.

When administering the product to kittens, the administrator should be careful not to administer more than the recommended dose/weight. For kittens weighing less than 0.5 kg, a 1 ml syringe which allows proper dosing should be used.

Treat the animal by slowly and gently injecting the liquid into the mouth, allowing the cat to swallow the product.

After dosing, the syringe should be removed from the bottle, washed and dried and the cap should be screwed back on tightly.

Data in humans shows that food intake may result in lower drug absorption. Therefore, it is recommended to administer the product by preference between meals.

In some cases, a prolonged time between clinical and mycological cure may be observed. In cases where a positive culture is obtained 4 weeks after the end of administration, the treatment should be repeated once at the same dosage regimen. In such cases where the cat is also immunosuppressed, treatment should be repeated and the underlying disease addressed.

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

After a 5x overdose of itraconazole administered for 6 consecutive weeks, reversible clinical side effects were: rough hair coat, decreased food intake and reduced body weight . A 3x overdose for 6 weeks did not result in clinical side effects. Both after a 3x and a 5x overdose for 6 weeks, reversible change in serum biochemical parameters indicating liver involvement occur (increased ALT, ALP, bilirubin and AST). At 5 times overdose a slight increase in segmented neutrophils and a slight decrease in lymphocytes were observed.

No studies on overdose in kittens have been performed.

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

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ02AC02

4.2 Pharmacodynamics

Itrafungol contains itraconazole, a synthetic broad spectrum triazole antimycotic with a high activity against dermatophytes (*Trichophyton* spp, *Microsporum* spp.), yeasts (*Candida* spp., *Malassezia* spp.), various dimorphic fungi, zygomycetes and eumycetes (e.g. *Aspergillus* spp.).

The mode of action of itraconazole is based on its highly selective binding ability to fungal Cytochrome P-450 iso-enzymes. This inhibits the synthesis of ergosterol and affects membrane-bound enzyme function and membrane permeability. This effect is irreversible and causes structural degeneration.

4.3 Pharmacokinetics

Laboratory animals rapidly absorb orally administered itraconazole. It binds very extensively to plasma proteins (>99 %) and distributes to tissues. More than 30 metabolites are formed, from which hydroxy-itraconazole has an antifungal activity as the parent. Excretion is rapid and mainly via the faeces.

In cats a single oral dose of 5 mg/kg results in maximum plasma concentrations of on average 0.525 mg/l attained 2 hours after dosing. The AUC0-24 h is 5 mg.h/l. The half-life in plasma is about 12 hours. After repeated administration for one week at 5 mg/kg/day, the maximum plasma concentration is more than doubled. The AUC0-24 h is increased 3 times to 15 mg.h/l and the plasma half-life is also increased 3 times to 36 hours.

In the therapeutic treatment schedule, itraconazole is almost completely cleared from plasma after each wash-out. In contrast to what happens in other animals, hydroxy-itraconazole remains near or below the quantification limit in plasma after a single dose of itraconazole at 5 mg/kg. Concentrations in cat's hair vary; an increase occurs during treatment to a median value of 3.0 µg/g (mean 5.2 µg/g) at the end of the third dosing week and concentrations drop slowly to 1.5 µg/g (mean 1.9 µg/g) at 14 days after the end of treatment. Concentrations of hydroxy-itraconazole in hair are insignificant.

Bioavailability of the oral solution of itraconazole in humans is higher when administered in fasted conditions.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after first opening the immediate packaging: 5 weeks.

5.3 Special precautions for storage

Do not store above 25°C.
Keep the container tightly closed.

5.4 Nature and composition of immediate packaging

Amber glass bottle (type III) containing 52 ml oral solution, closed with a child resistant polypropylene screw cap with a LDPE insert packed in a cardboard box with a graduated dosing syringe.

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.

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

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

<{MM/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 III

LABELLING AND PACKAGE LEAFLET

A. **LABELLING**

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Itrafungol 10 mg/ml Oral Solution
Itrafungol vet 10 mg/ml Oral Solution (DK, FI, NO, SE)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 10 mg itraconazole

3. PACKAGE SIZE

52 ml
with oral dosing syringe

4. TARGET SPECIES

Cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 5 weeks. Use by:_____

9. SPECIAL STORAGE PRECAUTIONS

Keep the container tightly closed.
Do not store above 25 °C.

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

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Itrafungol 10 mg/ml Oral Solution
Itrafungol vet 10 mg/ml Oral Solution (DK, FI, NO, SE)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 10 mg itraconazole

3. TARGET SPECIES

Cats

4. ROUTES OF ADMINISTRATION

Oral use
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp {mm/yyyy}
Once opened use within 5 weeks.

7. SPECIAL STORAGE PRECAUTIONS

Keep the container tightly closed.
Do not store above 25 °C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Itrafungol 10 mg/ml Oral Solution
Itrafungol vet 10 mg/ml Oral Solution (DK, FI, NO, SE)

2. Composition

Each ml contains:

Active substance:

Itraconazole	10 mg

Excipients:

Sorbitol 70% Non-crystallising Solution	245.1 mg
Propylene glycol (E1520)	103.6 mg
Caramel (E150)	0.2 mg

Yellow to slightly amber, clear solution.

3. Target species

Cats

4. Indications for use

Treatment of dermatophytosis in cats caused by *Microsporum canis.*

5. Contraindications

Do not use in cats with hypersensitivity to itraconazole or one of the other ingredients.
Do not use in cats with impaired liver or kidney function.
For use in pregnant and lactating queens: see special warnings.

6. Special warnings

Special warnings:
Some cases of feline dermatophytosis can be difficult to cure, especially in catteries. Cats treated with itraconazole can still infect other cats with *M. canis* as long as they are not mycologically cured. It is therefore advised to minimise the risk of re-infection or spread of infection by keeping healthy animals (including dogs as they can also be infected by *M. canis*) separate from cats that are being treated. Cleaning and disinfection of the environment with appropriate fungicidal products is highly recommended – especially in case of group problems. Treatment of dermatophytosis should not be limited to treatment of the infected animal(s). It should also include disinfection of the environment with appropriate fungicidal products, since *Microsporum canis* spores can survive in the environment for up to 18 months.

Other measures such as frequent vacuuming, disinfection of grooming equipment and removal of all potentially contaminated material that cannot be disinfected will minimize the risk of re-infection or spread of infection.

It is strongly recommended that clipping is performed by a veterinarian.
Clipping of the hair coat is considered useful because it removes infected hairs, stimulates new hair growth and hastens recovery. In cases with limited lesions, hair clipping can be limited to the lesions only, whereas in cats with generalized dermatophytosis it is recommended to clip the entire hair coat. Care should be taken not to cause trauma to the underlying skin during hair clipping. Furthermore it is recommended that disposable, protective clothing and gloves are worn during the clipping of affected animals. The hairs should be disposed of appropriately and all instruments, clippers etc. should be disinfected.

Measures to prevent introduction of *M.canis* into groups of cats may include isolation of new cats, isolation of cats returning from shows or breeding, exclusion of visitors and periodic monitoring by Wood's lamp or by culturing for *M.canis*.

In refractory cases, the possibility of an underlying disease should be considered.

Frequent and repeated use of an antimycotic may result in the induction of resistance to antimycotics of the same class.

Special precautions for safe use in the target species:
Cats suffering from dermatophytosis, but also in poor general condition and/or suffering from additional diseases or impaired immunological response should be monitored closely during treatment. Because of their condition, this category of animals may be more sensitive to the development of adverse effects. In case of a serious adverse effect, treatment should be interrupted and supportive care therapy (fluid therapy) should be initiated if necessary. If clinical signs suggestive of liver dysfunction develop, treatment should be discontinued immediately. It is very important to monitor liver enzymes in animals showing signs of liver dysfunction.

In humans, itraconazole has been associated with heart failure due to a negative inotropic effect. Cats suffering from heart diseases should be carefully monitored and the treatment should be withdrawn if the clinical signs deteriorate.

Special precautions to be taken by the person administering the veterinary medicinal products to animals:
If a suspected lesion occurs on a human, consult a physician, since M. canis dermatophytosis is a zoonotic disease. Therefore, wear latex gloves when clipping hair of infected cats, when handling the animal during treatment or when cleaning the syringe.
Wash hands and exposed skin after use. In case of accidental contact with eyes, rinse thoroughly with water. In case of pain or irritation, seek medical advice immediately and show the package leaflet or the label to the physician. In case of accidental ingestion, rinse mouth with water.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
Do not use in pregnant or lactating queens.

Interaction with other medicinal products and other forms of interaction:
Vomiting, hepatic and renal disorders were seen after concomitant treatment of Itrafungol and cefovecin. Symptoms like motor incoordination, faecal retention and dehydration are observed when tolfenamic acid and Itrafungol are given simultaneously. Co-administration of the product and these drugs, in absence of data in cats, should be avoided.

In human medicine, interactions between itraconazole and certain other drugs have been described, resulting from interactions with drug metabolising enzymes eg cytochrome P450. It is not known to what extent these interactions are relevant for cats, but in the absence of data, co-administration of the product and the following drugs should be avoided:

Oral midazolam, cyclosporin, digoxin, chloramphenicol, ivermectin, methylprednisolone or oral anti-diabetic agents (increased plasma concentration of these may occur); barbiturates or phenytoin (decreased efficacy of these may occur); antacids (may cause reduced absorption of itraconazole); erythromycin (may cause increased plasma concentration of itraconazole).
Interactions in humans between itraconazole and calcium antagonists have also been reported. These drugs might have additive negative inotropic effects to the heart.

Overdose:
After a 5x overdose of itraconazole administered for 6 weeks, reversible clinical side effects can be seen: rough hair coat, decreased food intake and reduced body weight gain. A 3 x overdose for 6 weeks did not result in clinical side effects. Both after a 3 x and a 5 x overdose for 6 weeks, reversible adaptive liver changes may occur (increased bilirubin, AST, ALT and AP). No studies on overdose in kittens have been performed.

7. Adverse events

Common (1 to 10 animals / 100 animals treated):
Vomiting, Diarrhoea, Increased salivation Anorexia, Depression, Apathy[1]
Rare (1 to 10 animals / 10,000 animals treated):
Elevated liver enzymes[2,3,4]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Weight loss Elevated total bilirubin[3,4] (may be associated with icterus)

[1] These effects are usually mild and transient.
[2] Transient.
[3] If clinical signs suggestive of liver dysfunction develop, treatment should be discontinued immediately.
[4] Sometimes fatal.

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 or the local representative of 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

Oral use.
The solution is administered directly into the mouth by means of the enclosed graduated dosing syringe.

The daily dosage is 5 mg (0.5 ml)/kg bodyweight per day, for 3 alternate periods of 7 consecutive days of treatment followed by 7 days without treatment.

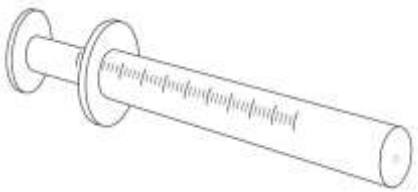
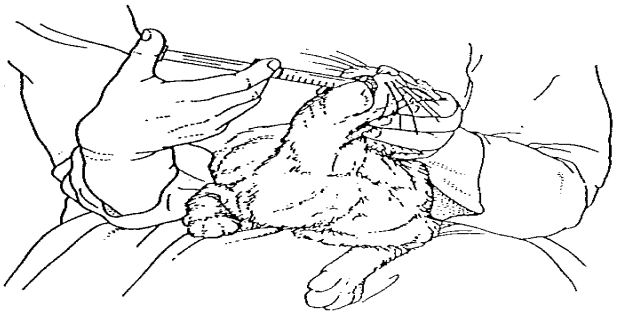
9. Advice on correct administration

The dosing syringe shows graduations per 100 gram of body weight. Fill the syringe by pulling the plunger until the correct body weight of the cat is indicated on the syringe (Fig. 1).
Treat the animal by slowly and gently injecting the liquid into the mouth, allowing the cat to swallow the product (Fig. 2). When administering the product to kittens, the administrator should be careful not to administer more than the recommended dose/weight. For kittens weighing less than 0.5 kg, a 1 ml syringe which allows proper dosing should be used.

Data in humans shows that food intake may result in lower drug absorption. Therefore, it is recommended to administer the product by preference between meals.

Clinical studies have indicated that the time period between clinical and mycological cure may vary. It is therefore advised to minimise the risk of re-infection or spread of infection by keeping healthy animals separate from animals that are being treated. Cleaning and disinfection of the environment with appropriate products is highly recommended – especially in case of group problems.

In some cases, a prolonged time between clinical and mycological cure may be observed. In cases where a positive culture is obtained 4 weeks after the end of administration, the treatment should be repeated once at the same dosage regimen. In such cases where the cat is also immunosuppressed, treatment should be repeated and the underlying disease addressed.

Fig 1	Fig. 2
	

After dosing the syringe should be removed from the bottle, washed and dried and the cap should be screwed back on tightly.

Avoid contamination of the solution.

10. Withdrawal periods

Not applicable

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 °C.
Keep the container tightly closed.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 5 weeks.

12. Special precautions for disposal

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

Cardboard box with 1 x 52 ml bottle and a dosing syringe.

15. Date on which the package leaflet was last revised

Date to be inserted
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:
VIRBAC
1ère avenue – 2065 m – L.I.D.
06516 Carros
France

Manufacturer responsible for batch release:
Lusomedicamenta, Sociedade Técnica
Farmacêutica, S.A.
Estrada Consiglieri Pedroso, n°69-B
Queluz de Baixo
2730-055 Barcarena, Portugal

Local representative(s) and contact details to report suspected adverse reactions:

17. Other information

The mode of action of itraconazole is based on its binding ability to fungal Cytochrome P-450 iso-enzymes. This inhibits the synthesis of ergosterol and affects membrane-bound enzyme function and membrane permeability. This effect is irreversible and causes structural degeneration.