PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Itrafungol® 10 mg/ml Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: 10 mg itraconazole

3. PHARMACEUTICAL FORM

Oral Solution

4. PACKAGE SIZE

52 ml
with oral dosing syringe

5. TARGET SPECIES

Cat
<pictogram of cat profile>

6. INDICATION(S)

For the treatment of dermatophytosis in cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

0.5 ml/kg/day for 3 alternate periods of 7 consecutive days of treatment, followed by 7 days without treatment.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Contraindications
Do not administer to cats with hypersensitivity to itraconazole or one of the other ingredients. Do not administer to cats with impaired liver or kidney function.
Do not use in pregnant or lactating queens.

10. EXPIRY DATE

Expiry: <*MM-YYYY*>
Shelf-life after first opening of the container: 5 weeks. Discard date:_____

11. SPECIAL STORAGE CONDITIONS

Keep bottle in the outer carton.
Do not store above 25 °C.
Avoid contamination of the solution.

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

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

Legal category:
POM-V To be supplied only on veterinary prescription

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4228

17. MANUFACTURER'S BATCH NUMBER

Batch No: <*number*>

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Itrafungol® 10 mg/ml Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: 10 mg itraconazole

3. PHARMACEUTICAL FORM

Oral Solution

4. PACKAGE SIZE

52 ml

5. TARGET SPECIES

Cat

6. INDICATION(S)

For the treatment of dermatophytosis in cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Expiry: <*MM-YYYY*>
Shelf-life after first opening of the container: 5 weeks.

11. SPECIAL STORAGE CONDITIONS

Keep bottle in the outer carton.
Do not store above 25 °C.

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

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

Legal category:
POM-V To be supplied only on veterinary prescription

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4228

17. MANUFACTURER'S BATCH NUMBER

Batch No: <*number*>

PACKAGE LEAFLET
Itrafungol® 10 mg/ml Oral Solution

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

Marketing Authorisation Holder:
VIRBAC
1ère avenue 2065m LID
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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Itrafungol 10 mg/ml Oral Solution

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

Itrafungol is a yellow to slightly amber coloured clear oral solution containing itraconazole as active ingredient.
Each ml contains: itraconazole 10 mg/ml
Other ingredients include: propylene glycol, sorbitol, and caramel (E150)

4. INDICATION(S)

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

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Salivation, vomiting, diarrhoea, anorexia, depression and apathy may occur. These effects are usually mild and transient.
In very rare cases a transient increase in liver enzymes may occur. In very rare cases, this may be associated with icterus. If clinical signs suggestive of liver dysfunction develop, treatment should be discontinued immediately.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats

For Animal Treatment Only

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

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.

7 days	7 days	7 days	7 days	7 days
treatment	no treatment	treatment	no treatment	treatment

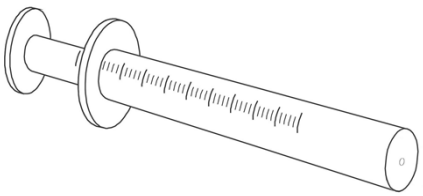
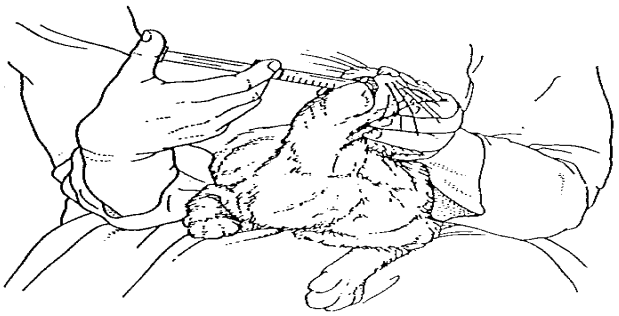
9. ADVICE ON CORRECT ADMINISTRATION

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 PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Keep the bottle in the outer carton.

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

Shelf-life after first opening of the container: 5 weeks. When the container is opened for the first time, the date on which any product remaining in the container should be discarded should be calculated. A statement of the in-use shelf life of the product is given on this leaflet. This discard date should be written on the space provided on the carton.

Do not use after the expiry date stated on the label and carton.

12. SPECIAL WARNING(S)

Special warnings for each target species
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.

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.

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

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*.

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

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

Interactions with other drugs
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.

Special precautions to be taken by the person administering the medicinal products to animals
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. In case of accidental ingestion, rinse mouth with water.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2021

15. 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.

Presentation
Amber glass bottle containing 52 ml oral solution, packed in a cardboard box with a graduated dosing syringe.

Legal category
POM-V To be supplied only on veterinary prescription

Marketing Authorisation number/s
Vm 05653/4228

Approved: 13/07/21