ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fugasol 10 mg/ml oral solution for cats
Itraconazole

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Itraconazole 10 mg

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

1x 25 ml bottle
1x 50 ml bottle
1x 100 ml bottle

5. TARGET SPECIES

Cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

Exp {mm/yyyy}
Shelf life after first opening the immediate packaging: 90 days

11. SPECIAL STORAGE CONDITIONS

Keep the container tightly closed.

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

Dispose of waste material in accordance with local requirements.

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

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

16. MARKETING AUTHORISATION NUMBERS

Vm 20916/3003

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGE

Amber glass or white high density polyethylene (HDPE) bottles, 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fugasol 10 mg/ml oral solution for cats
Itraconazole

2. STATEMENT OF ACTIVE SUBSTANCES

Itraconazole 10 mg/ml

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

1x 100 ml

5. TARGET SPECIES

Cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 90 days

11. SPECIAL STORAGE CONDITIONS

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

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 20916/3003

17. MANUFACTURER'S BATCH NUMBER

Batch number:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Amber glass or white high density polyethylene (HDPE) bottles, 25 ml, 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fugasol 10 mg/ml oral solution for cats
Itraconazole

2. QUANTITY OF THE ACTIVE SUBSTANCES

Itraconazole 10 mg/ml

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

25 ml bottle
50 ml bottle

4. ROUTE(S) OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

Exp {mm/yyyy}
Shelf life after first opening the immediate packaging: 90 days

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Fugasol 10 mg/ml oral solution for cats

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

Marketing authorisation holder and manufacturer responsible for batch release:
CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fugasol 10 mg/ml oral solution for cats
Itraconazole

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

Each ml contains

Active substance:
Itraconazole 10 mg

Oral solution.
Slight yellow to brownish, clear to slight opalescent solution.

4. INDICATION(S)

Treatment of dermatophytosis (a fungal infection also known as ringworm) caused by *Microsporum canis.*

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to itraconazole, to other azoles or any of the other excipients.
Do not use in cases of impaired liver or kidney function.
Do not use in pregnant or lactating queens.

6. ADVERSE REACTIONS

Some form of adverse reaction possibly related to the administration of the product were noted in clinical studies. Common adverse reactions were vomiting, diarrhoea, anorexia, salivation, depression and apathy. These effects are usually mild and transient. In very rare cases a transient increase in liver enzymes may occur. In very rare cases this was associated with icterus (yellow discoloration of eyes and skin). If

clinical signs suggestive of liver dysfunction develop, treatment should be discontinued immediately.

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. Alternatively you can report via your national reporting system {national system details}

7. TARGET SPECIES

Cats.

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

For oral use.

Administer 5mg of itraconazole per kg body weight once daily, equivalent to 0.5 mL of the product per kg body weight once daily. The solution should be administered directly into the mouth by means of a dosing syringe.

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.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require and special storage conditions.
Keep the container tightly closed.
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 of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after first opening the immediate packaging: 90 days

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.

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.

Special precautions for use in animals:
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 product to animals:

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. If a suspected lesion occurs on a human, consult a physician.

This veterinary medicinal product may cause skin and/or eye irritation. Avoid contact with skin and eyes. Wash hands and exposed skin after use. In case of accidental contact with eyes, rinse thoroughly with water. In case of persistent pain or irritation, seek medical advice and show the label or package leaflet to the physician.

This product may be harmful after accidental ingestion by children. Do not leave the filled syringe unattended. In case of accidental ingestion, rinse mouth with water, seek medical advice immediately and show the package leaflet or the label to the physician. This product may cause hypersensitivity reactions. People with known hypersensitivity to itraconazole or propylene glycol should avoid contact with the veterinary medicinal product. Wash hands after use.

Pregnancy and lactation:
Do not use in pregnant or lactating queens.
Malformations and foetal resorptions were seen in overdose studies in laboratory animals. Laboratory studies in rats have shown evidence of dose-related teratogenic, foetotoxic and maternotoxic effects at high dosages (40 and 160 mg/kg bw/day for 10 days during their gestational period).

The safety of the product was not assessed in pregnant or lactating cats.

Interaction with other medicinal products and other forms of interaction:
Vomiting, hepatic and renal disorders were seen after concomitant treatment of itraconazole and cefovecin. Symptoms like motor incoordination, faecal retention and dehydration are observed when tolfenamic acid and itraconazole 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.

Overdose:
After a 5 times overdose of itraconazole administered for 6 consecutive weeks, reversible clinical side effects were: rough hair coat, decreased food intake and reduced body weight . A 3 times overdose for 6 weeks did not result in clinical side effects. Both after a 3 times and a 5 times 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.

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

Ask your veterinary surgeon or pharmacist 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

15. OTHER INFORMATION

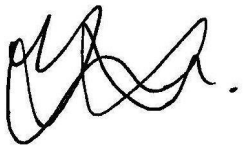
Amber glass or white high density polyethylene (HDPE) bottles with child resistant polypropylene screw cap and low density polyethylene (LDPE) syringe in-lay.
Measuring device: Syringe (3 ml) with low density polyethylene (LDPE) body and polystyrene (PS) plunger.

Each bottle contains: 25 ml, 50 or 100 ml

Package size:
Cardboard box with 1 bottle of 25, 50 or 100 ml and an oral syringe of 3 ml as dosing device.

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.



Approved: 15 December 2022