[Version 8.2,01/2021]

ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (52 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Itracovet 10 mg/ml oral solution for cats
Itraconazole

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Itraconazole 10 mg/ml

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

52 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)

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life of the veterinary medicinal product as packaged for sale: 6 months
Once opened, use by 5 weeks

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.

Do not refrigerate or freeze.
Keep the bottle tightly closed.
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

AB7 Santé
Chemin des Monges
31450 Deyme
France

16. MARKETING AUTHORISATION NUMBER(S)

<To be completed in accordance to National Authorisation after conclusion of the DC/MR phase>.

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial (52 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Itracovet 10 mg/ml oral solution for cats
Itraconazole

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Itraconazole 10 mg/ml

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

52 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)

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life of the veterinary medicinal product as packaged for sale: 6 months
Once opened, use by 5 weeks.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC.

Do not refrigerate or freeze.
Keep the bottle tightly closed.
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

AB7 Santé
Chemin des Monges
31450 Deyme
France

16. MARKETING AUTHORISATION NUMBER(S)

<To be completed in accordance to National Authorisation after conclusion of the DC/MR phase>.

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Itracovet 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 for batch release:
AB7 Santé
Chemin des Monges
31450 Deyme
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Itracovet 10 mg/ml oral solution for cats

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

Itracovet is a slightly brown to amber, clear solution.

Each ml contains:

Active substance:

Itraconazole	10 mg

Excipients:

Caramel (E150)	0.2 mg
Propylene glycol (E1520)	103.6 mg
Sorbitol, liquid (non-crystallising)	245.1 mg

4. INDICATION(S)

Treatment of dermatophytosis caused by *Microsporum canis.*

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to itraconazole, to other azoles or to any of the excipients.
Do not use in cases of impaired liver or kidney function.
Do not use in pregnant and lactating queens (see section 12).

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. 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

9. ADVICE ON CORRECT ADMINISTRATION

The dosing syringe shows graduations per 200 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 and the underlying disease addressed.

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

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 container: 5 weeks.

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 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.

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.

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.

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.
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).

Interaction with other medicinal products and other forms of interaction:
Vomiting, hepatic and renal disorders were seen after concomitant treatment of the veterinary medicinal product and cefovecin. Symptoms like motor incoordination, faecal retention and dehydration are observed when tolfenamic acid and the veterinary medicinal product 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 (symptoms, emergency procedures, antidotes):
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:

None known.

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

Any unused product or waste material should be disposed of in accordance with national requirements. 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

15. OTHER INFORMATION

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

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