

Itrafungol[®]

(itraconazole oral solution)

10 mg/ml
Antifungal for oral use in cats only

Caution:

Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Description:

ITRAFUNGOL oral solution is a yellow to slightly amber, clear solution containing the active ingredient, itraconazole, at 10 mg/mL.

Indication:

ITRAFUNGOL oral solution is indicated for the treatment of dermatophytosis caused by *Microsporum canis* in cats.

Dosage and Administration:

The solution should be administered orally using the enclosed graduated dosing syringe.

The daily dosage is 5 mg/kg (0.5 mL/kg) body weight administered once daily on alternating weeks for 3 treatment cycles. Cats are treated during weeks 1, 3, and 5, and left untreated during weeks 2 and 4.

7 days	7 days	7 days	7 days	7 days
Daily treatment	No Treatment	Daily treatment	No Treatment	Daily treatment

Each line on the dosing syringe represents 0.05 mL of oral solution.

Table 1: Dose Table for ITRAFUNGOL

Weight of Cat	Volume of ITRAFUNGOL
0.5 lb	0.1 mL
1.0 lb	0.2 mL
1.5 lb	0.35 mL
2.0 lb	0.45 mL
2.5 lb	0.55 mL
3.0 lb	0.7 mL
3.5 lb	0.8 mL
4.0 lb	0.9 mL
4.5 lb	1.0 mL
5.0 lb	1.15 mL
6.0 lb	1.35 mL
7.0 lb	1.6 mL
8.0 lb	1.8 mL
9.0 lb	2.0 mL
10.0 lb	2.25 mL
11.0 lb	2.5 mL
12.0 lb	2.7 mL
13.0 lb	3.0 mL

The solution should be administered orally using the enclosed graduated dosing syringe. Keep the bottle upright and insert the dosing syringe through the opening of the top of the bottle (Figure 1).

Do not invert the bottle (Figure 2). Fill the syringe by pulling the plunger until it reaches the graduation corresponding to the correct mL dose as indicated at the top of the syringe ring (Figure 3). Treat the cat by slowly and gently administering the liquid into the mouth, allowing the cat to swallow the product (Figure 4). For cats weighing more than 13.0 lbs, the total dose will need to be calculated and given over two doses as the dosing syringe only holds 3.0 mL of solution.

Fig. 1



Fig. 2



Fig. 3

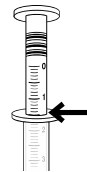


Fig. 4



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

Contraindications:

Do not administer to cats with hypersensitivity to itraconazole.

Warnings:

ITRAFUNGOL (itraconazole oral solution) has not been shown to be safe in pregnant cats (see Animal Safety section). ITRAFUNGOL should only be used in pregnant or lactating cats when the benefits outweigh the potential risks.

User Safety Warnings:

Not for use in humans. Keep this and all medications out of reach of children. 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 and seek medical advice.

Special precautions for person administering the veterinary product to the animal:

Microsporum canis dermatophytosis is a zoonotic disease (a disease that can be transmitted from animals to humans); therefore consult a physician if a suspected lesion occurs on a human. Wear protective gloves when handling the animal during treatment or when cleaning the syringe. Wash hands and exposed skin after handling the animal.

ITRAFUNGOL has not been shown to be sporicidal; therefore in order to reduce zoonotic potential, environmental contamination, and to decrease course of the disease, topical and environmental treatment should also be utilized.

Precautions:

ITRAFUNGOL has been associated with renal changes found on histopathology that were not noted after an eight week recovery period (see Animal Safety). Use with caution in cats with renal dysfunction.

ITRAFUNGOL is metabolized by the liver (mainly CYP3A) and can cause elevated liver enzymes (see Animal Safety section). Use with caution in cats with impaired liver function. If clinical signs suggestive of liver dysfunction develop, treatment should be discontinued.

ITRAFUNGOL is a cytochrome p-450 inhibitor and may increase or prolong plasma concentrations of other drugs metabolized by this pathway, such as amitriptyline, amlodipine, benzodiazepines, buspirone, cisapride, corticosteroids, cyclosporine, ivermectin, and macrolide antibiotics.

Negative inotropic effects have been reported in literature when itraconazole was administered intravenously to dogs and healthy human volunteers. Cats suffering from heart disease should be carefully monitored during treatment.

Adverse Reactions:

In the laboratory effectiveness study, adverse reactions related to exposure to ITRAFUNGOL were primarily related to the gastrointestinal tract. Two ITRAFUNGOL-treated cats experienced transient hypersalivation during the dosing period. Vomiting was observed in 5 ITRAFUNGOL-treated cats (12.5%) during the dosing period compared to four cats (10%) in the control group. Diarrhea was observed in 9 ITRAFUNGOL-treated cats (22.5%) during the dosing period as compared to 7 cats (17.5%) in the control group.

One ITRAFUNGOL-treated cat showed mild increases in alanine aminotransferase (ALT) and aspartate aminotransferase (AST) at the end of the dosing period. No related clinical signs were observed, and these values returned to normal by the end of the follow-up period. One cat in the ITRAFUNGOL-treated group was noted to have lip erythema and lip induration once during the study.

Field safety was evaluated in 266 cats randomized to receive itraconazole oral solution. Of the 266 cats that received at least one dose of itraconazole oral solution, adverse reactions included 35 cases (13%) of one or more elevated hepatic enzymes and 8 cases (3%) of gastrointestinal upset, including decreased appetite, vomiting and/or diarrhea. Other infrequent adverse reactions included less than 3 cases each of somnolence, depression, and increased salivation.

For technical assistance or to report suspected adverse drug events, contact Elanco Animal Health at 1-888-545-5973.