

For the use only of a Registered Veterinary Practitioner, Hospital or Laboratory

## FELINTRA

(Itraconazole Oral Solution BP)

### Composition:

Each ml contains:  
Itraconazole IP 10mg  
Flavored base q.s.

**Description:** Felintra is the brand name for itraconazole, an azole antifungal agent. Itraconazole is a 1:1:1:1 racemic mixture of four diastereomers (two enantiomeric pairs), each possessing three chiral centers. Felintra oral solution is a yellow to slightly amber, clear solution containing the active ingredient, itraconazole, at 10 mg/mL.

**Chemistry:**  $(\pm)$ -1-[(RS)-sec-butyl]-4-[p-[4-[p-[(2R,4S)-2-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy]phenyl]-1-piperazinyl]phenyl]- $\Delta$ 2-1,2,4-triazolin-5-one

### Clinical Pharmacology:

#### Pharmacodynamics:

The mode of action of FELINTRA (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 of the fungal organism.

#### Pharmacokinetics:

Itraconazole was absorbed rapidly following oral administration of FELINTRA (Itraconazole oral solution) to cats. Compared to the fasted state, administration of FELINTRA with food results in slightly higher (1.3 fold) mean total itraconazole exposure. FELINTRA can be administered with or without food. Itraconazole oral solution binds extensively to plasma proteins (> 99%), and distributes throughout the tissues. Excretion is rapid and primarily via the feces.

In cats, a single oral dose of 5 mg/kg results in a C<sub>max</sub> of 0.525 µg/ml post dose at 2 hours (T<sub>max</sub>). The AUC<sub>0-24h</sub> is 5.09 µg.h/ml and the half-life in plasma is 12.1 hours. After repeated daily administration for seven days at 5 mg/kg/day, the C<sub>max</sub> is doubled (1.05 µg/ml), the AUC<sub>0-24h</sub> is increased 3-fold (15.4 µg.h/ml) and the plasma half-life is increased to 36 hours.

In the therapeutic treatment schedule, itraconazole is almost completely cleared from plasma after each wash-out period. The hydroxy-itraconazole remains near or below the quantification limit in feline plasma after a single dose of itraconazole oral solution at 5 mg/kg. However, after repeated daily doses of itraconazole oral solution at 5 mg/kg for one week, the hydroxy-itraconazole C<sub>max</sub> of 0.059 µg/ml was reached at 2 hours (T<sub>max</sub>). Itraconazole 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 final dosing. Concentrations of hydroxy-itraconazole in hair are insignificant.

#### Indications:

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

#### Dosage and Administration:

Cats: 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.

Week 1	Week 2	Week 3	Week 4	Week 5
7 days	7 days	7 days	7 days	7 days
Daily treatment	No treatment	Daily treatment	No treatment	Daily treatment

#### Contraindications:

Do not administer to cats with hypersensitivity to itraconazole.

**Warnings:** FELINTRA (itraconazole oral solution) has not been shown to be safe in pregnant cats. FELINTRA should only be used in pregnant or lactating cats when the benefits outweigh the potential risks.

**Adverse Effects:** Adverse effects related to gastrointestinal tract may occur.

**Interactions:** The following drug interactions have been reported in animals receiving Itraconazole:

- *Amphotericin B*: Lab animal studies have shown that itraconazole used concomitantly with amphotericin B may be antagonistic against *Aspergillus* or *Candida*.
- *Antacids*: May reduce oral absorption of itraconazole; administer itraconazole at least 1 hour before or 2 hours after antacids.
- *Benzodiazepines (alprazolam, diazepam, midazolam, triazolam)*: Itraconazole may increase levels
- *Buspirone*: Plasma concentrations may be elevated
- *Busulfan*: Itraconazole may increase levels
- *Calcium-channel blocking agents (amlodipine, verapamil)*: Itraconazole may increase levels
- *Cisapride*: Itraconazole may increase cisapride levels.
- *Corticosteroids*: Itraconazole may inhibit the metabolism of corticosteroids; potential for increased adverse effects
- *Cyclophosphamide*: Itraconazole may inhibit the metabolism of cyclophosphamide and its metabolites; potential for increased toxicity
- *Cyclosporine*: Increased cyclosporine levels.
- *Digoxin*: Itraconazole may increase digoxin levels.
- *Fentanyl/Alfentanil*: Itraconazole may increase fentanyl or alfentanil levels
- *H2-Blockers (ranitidine, famotidine, etc.)*: Increased gastric pH may reduce itraconazole absorption
- *Ivermectin*: Itraconazole may increase risk for neurotoxicity
- *Macrolide antibiotics (erythromycin, clarithromycin)*: May increase itraconazole concentrations
- *Phenobarbital/Phenytoin*: May decrease itraconazole levels

- *Proton-pump inhibitors (omeprazole, etc.)*: Increased gastric pH may reduce itraconazole absorption.
- *Quinidine*: Itraconazole may increase digoxin levels.
- *Rifampin*: May decrease itraconazole levels; itraconazole may increase rifampin levels
- *Sulfonylurea Antidiabetic Agents (e.g., glipizide, glyburide)*: Itraconazole may increase levels; hypoglycemia possible
- *Vincristine/Vinblastine*: Itraconazole may inhibit vinca alkaloid metabolism and increase levels
- *Warfarin*: Itraconazole may cause increased prothrombin times in patients receiving warfarin or other coumarin anticoagulants

**Presentation:** Pack of 60ml with dosing syringe.

**Storage:** Store in a dry place at a temperature not exceeding 25°C. Protect from light.

Keep out of reach of children.

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