For the use of Registered Veterinary Practitioner, Hospital or Laboratory

K-PET®

(Ketoconazole Tablets IP)

Composition:
Each Uncoated Tablet of K-PET® contains:
Ketoconazole IP 200 mg
Excipients q.s.

Description:
K-PET® is chewable tablet containing 200 mg of ketoconazole. Ketoconazole is a synthetic imidazole antifungal agent. The full chemical name for ketoconazole is 1-[4-(4-{[(2R,4S)-2-(2,4-Dichlorophenyl)-2-(1H-imidazol-1-ylmethyl)-1,3-dioxolan-4-yl]methoxy}phenyl)piperazin-1-yl]ethan-1-one.

Clinical Pharmacology:
Pharmacodynamics:
Ketoconazole blocks the synthesis of ergosterol, a key component of the fungal cell membrane, through the inhibition of cytochrome P-450 dependent enzyme lanosterol 14α-demethylase responsible for the conversion of lanosterol to ergosterol in the fungal cell membrane. This results in an accumulation of methylated sterol precursors and a depletion of ergosterol within the cell membrane thus weakening the structure and function of the fungal cell membrane.

Pharmacokinetics:
Ketoconazole is well absorbed orally in acidic environment. Ketoconazole is highly protein bound (>98%) and therefore does not penetrate into the cerebrospinal, seminal, or ocular fluid to a significant degree; although it is found in mother's milk. It distributes throughout the skin and subcutaneous tissue, making it effective for treatment of superficial and systemic fungal skin infections. The drug demonstrates nonlinear absorption and elimination kinetics, most probably due to saturation of metabolizing enzymes. It is biotransformed in the liver via O-dealkylation and aromatic hydroxylation and excreted mainly in the bile. Elimination half-life is approximately 2 hours in dogs.

Microbiology:
Ketoconazole is most effective against yeast and dimorphic fungi such as *Candida*, *Malassezia pachydermatis*, *Coccidioides immitis*, *Histoplasma capsulatum* and *Blastomyces dermatitidis*, as well as most dermatophytes with MIC values less than 0.5 µg/ml. It is less effective against *Cryptococcus neoformans, S. schenckii*, and *Aspergillus* spp., with MIC values varying from 6 to >100 µg/ml.

Indications:
Ketoconazole has been used to treat several fungal infections like in dogs, cats, and other small species. It is used for systemic mycoses, including Dermatophytosis (Ringworm), Malassezia dermatitis, Aspergillosis, Cryptococcosis, Coccidiodomycosis, Histoplasmosis and Blastomycosis in dogs and cats; also used as an alternative treatment of hyperadrenocorticism in dogs.

Dosage and Administration:
For Dogs: Recommended oral dose range is 5-15 mg/kg twice a day (give with food).
For Cats: Recommended oral dose range is 5-10 mg/kg twice a day (give with food).
The dosage should be chosen based on the clinical condition of the dog/cat. The effects of the treatment may not be seen for one or two weeks and the treatment duration may extend for several months.

Warnings and Precautions:
Do not use K-PET® Tablets in pregnant or lactating dogs or cats
It is advised not to use the medication in animals with liver disease, clotting problems and those allergic to the ketoconazole.
Ketoconazole has potential to cause birth defects.
Ketoconazole is absorbed into the body best when it is given with food.

Keep this drug out of the reach of children.

For use in dogs and cats
NOT FOR HUMAN USE
FOR ANIMAL TREATMENT ONLY

Adverse Reactions:
The most commonly observed side effects include vomiting, diarrhea, nausea, lethargy, itching, inflammation and loss of appetite. These may be reduced by giving ketoconazole with food or by dividing the dose into several smaller doses. If nausea is severe, it should resolve with discontinuation of the medication.
Side effects may also occur like liver damage and blood disorders.
Ketoconazole interferes with testicular secretion of testosterone and may produce a feminizing effect in males.

Drug Reactions:
Ketoconazole may increase the levels of some drugs which includes Benzodiazepines (midazolam, triazolam), Calcium-channel blocking agents (amlodipine, verapamil), Cisapride, Cyclosporine, Ivermectin, Digoxin, Fentanyl/Alfentanil,

Vincristine/Vinblastine, Warfarin, Sulfonylurea Antidiabetic Agents (*e.g.,* glipizide, glyburide), Rifampin and Quinidine.
Ketoconazole may reduce metabolism of some drugs which includes Corticosteroids, Cyclophosphamide, Antidepressants and Tricyclic (amitriptyline, clomipramine).

Antacids, H2-Blockers (ranitidine, famotidine, etc.), Proton-pump inhibitors (omeprazole, etc.) and Sucralfate may reduce oral absorption of ketoconazole.

Macrolide antibiotics (erythromycin, clarithromycin) may increase levels of ketoconazole. Ketoconazole may inhibit levels of Mitotane, phenytoin and Isonoazid.

Storage:
Store in cool and dry place below 30°C
Protect from lght

Presentation: 1 x 10 Tablets

SAVAVET
Shaping the Future

SAVA HEALTHCARE LIMITED
Plot No. 507-B to 512 GIDC Estate,
Wadhwan City – 363035, Surendranagar,
Gujarat, India
www.savavet.com