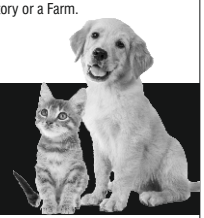
For the use only of a Registered Veterinary Practitioner or a Hospital or a Laboratory or a Farm.



Itraconazole Tablet 100 mg

ITRAZOO™ 100

Yum-Tab!

Antifungal For Systemic Mycoses for Dogs & Cats.

COMPOSITION:
Each uncoated tablet contains :
Itraconazole BP .....100 mg
Excipients.....q.s.

DESCRIPTION:
ITRAZOO contains Itraconazole, a synthetic broad spectrum triazole antimycotic with a high activity against dermatophytes (*Trichophyton* spp, *Microsporum* spp.), yeasts (*Candida* spp., *Malassezia* spp.), various dimorphic fungi, zygomycetes and eumycetes (e.g. *Aspergillus* spp.).

INDICATIONS:
Treatment of fungal infections that affect lungs, nails, mouth, throat, etc. Tinea caused by dermatophytes. Systemic, superficial and deep mycosis. As prophylaxis in patients with immune suppression.

DOSAGE AND ADMINISTRATION:
1 tablet every 10 to 20 kg/body weight (5 to 10 mg/kg).
Interval between doses and treatment duration: Every 24 hours for two consecutive days, suspending for 5 days, and repeating the treatment for at least 4 weeks, or until the remission of the symptoms.
Daily treatment (systemic mycoses): 1 tablet every 20 kg body weight (5 mg / kg), every 24 hours, for not less than 4 weeks or up to signs submission.

ADMINISTRATION: Oral

TARGET SPECIES: Dogs & Cats.

PHARMACODYNAMIC PROPERTIES:
Pharmacotherapeutic group: Antimycotics for systemic use, triazole derivates.
ATCvet code: QJ02AC02

PHARMACODYNAMICS:
The mode of action of 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.

PHARMACOKINETICS:
Itraconazole is rapidly absorbed when administered orally. It binds very extensively to plasma proteins (>99 %) and distributes to tissues. More than 30 metabolites are formed, from which hydroxy-itraconazole has an antifungal activity as the parent. Excretion is rapid and mainly via the faeces. In cats a single oral dose of 5 mg/kg results in maximum plasma concentrations of on average 0.525 mg/l attained 2 hours after dosing. The AUC0-24 h is 5 mg.h/l. The half-life in plasma is about 12 hours. After repeated administration for one week at 5 mg/kg/day, the maximum plasma concentration is more than doubled. The AUC0-24 h is increased 3 times to 15 mg.h/l and the plasma half-life is also increased 3 times to 36 hours.

WARNING & PRECAUTION:
In case of accidental ingestion by humans, seek medical advice immediately and show the package leaflet or the label to the physician.
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.

CONTRAINDICATIONS:
Do not administer in pregnant females, lactating animals or in patients with hepatic failure.
Hypersensitivity to any of the Ingredients.

ADVERSE EFFECTS :
Vomiting or diarrhoea within 24 hours of dosing was rarely observed. These effects are usually mild and transient. If clinical signs suggestive of liver dysfunction develop, treatment should be discontinued immediately.

WITHDRAWAL PERIOD: Not Applicable.

OVERDOSE: A 3x overdose for 6 weeks did not result in any clinical side effects.

STORAGE: Store below 30°C in a dry place.

PRESENTATION:
1 Blister containing 10 Tablets is packed in a Carton along with the Pack Insert.

VETERINARY.
NOT FOR HUMAN USE.
FOR ANIMAL TREATMENT ONLY.

KEEP OUT OF REACH OF CHILDREN & PETS, AWAY FROM FOOD.

Carefully read the accompanying instructions before use.

Veko

Manufactured & Marketed by:
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