fungiconazol® 200mg

Tablets for Dogs
Ketoconazole

Statement of the active substances and other ingredients
Each tablet contains:
Active substance:
Ketoconazole 200mg
Brown spiked, round flavoured tablets, divisible into equal halves and quarters.

Indications
Treatment of fungal infections caused by:
- *Microsporum canis,*
- *Microsporum gypseum,*
- *Trichophyton mentagrophytes.*

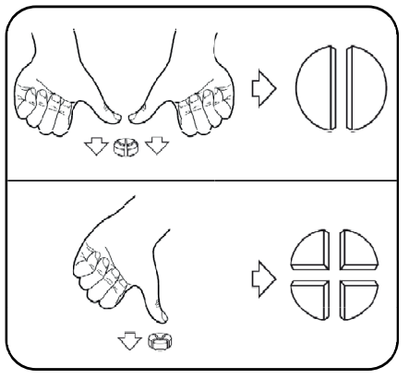
Contraindications
Do not administer to animals with liver failure.
Do not administer to animals with known hypersensitivity to the active substance or to any of the excipients.

Adverse reactions
In rare cases, neurological symptoms - apathy, ataxia, tremors (i.e. dog may seem passive, unstable and/or may have muscle spasms), hepatotoxicity (liver damage), vomiting, anorexia (severe lack of appetite) and/or diarrhoea may be observed at standard doses.
Ketoconazole has anti-androgen and anti-glucocorticoid effects; it inhibits the conversion of cholesterol to steroid hormones such as testosterone and cortisol in a dose-dependent and time-dependent manner. See also the Special warnings section for effects in male breeding dogs.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

Target species
Dogs.

Dosage for each species, routes and method of administration
10mg of ketoconazole per kg body weight daily, by oral administration. This corresponds to 1 tablet per 20kg body weight daily.
It is recommended to sample the animal once a month during treatment and to stop antifungal administration after two negative cultures. When mycological follow up is not possible, treatment should be continued for an adequate period of time to ensure mycological cure. If lesions persist after 8 weeks of treatment, medication should be re-evaluated by the responsible veterinarian.

Advice on correct administration
To be administered preferably together with food, in order to maximise absorption.
Tablets can be divided into equal halves or quarters to ensure accurate dosing. Put the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.
Equal Halves: With the tip of the thumbs, exert a slight vertical pressure on both sides of the tablet to break it into halves.
Equal quarters: With the tip of a thumb, exert a slight vertical pressure on the middle of the tablet to break it into quarters.



Special storage precautions
Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
In-use shelf life subdivided tablets (quarters/halves): 3 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP.

Special warnings
Although rare, repeated use of ketoconazole may induce cross-resistance to other azoles.
Special precautions for use in animals:
Treatment with ketoconazole suppresses testosterone concentrations and increases progesterone concentrations and may affect breeding effectiveness in male dogs during and for some weeks after treatment.
Treatment of dermatophytosis should not be limited to treatment of the infected animal(s). It should also include disinfection of the environment, since spores can survive in the environment for long periods of time. Other measures such as frequent vacuuming, disinfection of grooming equipment and removal of all potentially contaminated material that cannot be disinfected will minimise the risk of re-infection or spread of infection. Combination of systemic and topical treatment is recommended.
In case of long term treatment administration, liver function should be closely monitored. If clinical signs suggestive of liver dysfunction develop, treatment should be discontinued immediately.
Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to the active ingredients should avoid the contact of the skin and mucosae with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label.
Wash hands after use.
Part (half/quarter) tablets should be stored in the original blister and be used for the next administration. Keep the blister in the outer carton to prevent access by children.
Pregnancy and lactation:
Studies in laboratory animals have shown evidence of teratogenic and embryotoxic effects.
The safety of the product has not been established in pregnant or lactating bitches.
Use is not recommended during pregnancy.
Interaction with other medicinal products and other forms of interaction:
Do not administer with antacids and/or H2-receptor antagonists (cimetidine/ranitidine) or proton pump inhibitors (e.g. omeprazole) as the absorption of ketoconazole may be modified (absorption requires an acid environment).
Ketoconazole is a substrate and potent inhibitor of cytochrome P450 3A4 (CYP3A4). It may decrease the elimination of drugs metabolized by CYP3A4, thereby altering their plasma concentrations. Inducers of cytochrome P450 may increase the rate of metabolism of ketoconazole. Relevant veterinary interactions include cyclosporines, macrocyclic lactones (ivermectin, selamectin, milbemycin), midazolam, cisapride, amlodipine, fentanyl, macrolides (clarithromycin, erythromycin), digoxin, anticoagulants and phenobarbital.
Ketoconazole inhibits the conversion of cholesterol to cortisol and may thus affect trilostane / mitotane dosing in dogs concurrently being treated for hyperadrenocorticism.
Do not administer any other medicines to your dog without first consulting your veterinarian.
Overdose (symptoms, emergency procedures, antidotes):
In cases of overdose the following effects may be seen: anorexia (severe lack of appetite), vomiting, pruritus (itching), alopecia (loss of hair) and increase of some liver enzymes (ALT and ALP).
Incompatibilities:
Not applicable.

Special precautions for the disposal of unused product or waste material, if any
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Date on which the package leaflet was last approved: September 2014

Other information
Carton containing 1, 2, 3, 4, 5, 6, 7, 8, 9, 10
Aluminium/PVC/PE/PVDC blisters, containing 10 tablets each.
Not all pack sizes may be marketed.
To be supplied only on veterinary prescription.
For animal treatment only.

Marketing Authorisation Holder:
Le Vet Beheer B.V., Wilgenweg 7,
3421 TV Oudewater, The Netherlands

Manufacturer responsible for batch release:
Lelypharma B.V., Zuiveringweg 42, 8243 PZ Lelystad, The Netherlands

Distributed by:
Animalcare Ltd, 10 Great North Way, York, YO26 6RB, UK

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Vm 41821/4012
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VPA 10475/012/001
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