# PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fungiconazol 200 mg tablets

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Ketoconazole 200 mg

## 3. PACKAGE SIZE

10
20
30
40
50
60
70
80
90
100 tablets

## 4. TARGET SPECIES

Dogs.

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Oral use.

## 7. WITHDRAWAL PERIODS

## 8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life of divided tablets: 3 days.

## 9. SPECIAL STORAGE PRECAUTIONS

## 10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

## 11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

## 12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

## 13. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

## 14. MARKETING AUTHORISATION NUMBERS

Vm 50406/4027

## 15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Alu/PVC/PE/PVDC blisters}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fungiconazol

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Ketoconazole 200 mg/tablet

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}

# PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Fungiconazol 200 mg tablets for dogs

### 2. Composition

Each tablet contains:

**Active substance:**
Ketoconazole 200 mg

Brown spiked, round flavoured tablets, dividable into halves and quarters.

### 3. Target species

Dogs.

### 4. Indications for use

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

### 5. Contraindications

Do not use in animals with liver failure.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

### 6. Special warnings

Special warnings:
Although rare, repeated use of ketoconazole may induce cross-resistance to other azoles.

Special precautions for safe use in the target species:
Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.
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 minimize 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. As the tablets are flavoured, they should be stored in a safe place out of the reach of animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Accidental ingestion should be avoided. Keep the blister in the outer carton to prevent access by children. Part (half/quarter) tablets should be stored in the original blister and be used for the next administration. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
People with known hypersensitivity to ketoconazole should avoid contact with the veterinary medicinal product. Wash hands after use.

Other precautions:
Dermatophytes mentioned in the indication have zoonotic potential with risk of transmission to humans. Maintain good personal hygiene (washing hands after handling the animal and avoiding direct contact with animal). If signs of skin lesions occur, contact your physician.

Pregnancy and lactation:
Studies in laboratory animals have shown evidence of teratogenic and embryotoxic effects.
The safety of the veterinary medicinal 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/rantidine) 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. This may result in increased plasma concentrations of e.g. cyclosporine, macrocyclic lactones (ivermectin, selamectin, milbemycin), midazolam, cisapride, calcium-channel blocking agents, fentanyl, digoxin, macrolides, methylprednisolone or coumarine anticoagulants. The increased plasma

levels of drugs mentioned above can prolong the duration of effects as well as side effects.
On the other hand, inducers of cytochrome P450 may increase the rate of metabolism of ketoconazole, e.g. barbiturates or phenytoin can increase the rate of metabolism of ketoconazole, resulting in a decreased bioavailability, hence a decreased efficacy.
Ketoconazole may decrease theophylline serum concentrations.
Ketoconazole inhibits the conversion of cholesterol to cortisol and may thus affect trilostane / mitotane dosing in dogs concurrently being treated for hyperadrenocorticism.
It is not known to what extent these interactions are relevant for dogs and cats, but in the absence of data, co-administration of the veterinary medicinal product and these drugs should be avoided.
Do not administer any other medicines to your dog without first consulting your veterinarian.

Overdose:
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).

## 7. Adverse events

Dogs:

| | |
|---|---|
| Rare<br>(1 to 10 animals / 10,000 animals treated): | Neurological signs[a] (e.g. Ataxia (incoordination), Tremor)<br>Apathy[a], Anorexia[a]<br>Hepatic toxicosis (liver damage)[a]<br>Vomiting[a], Diarrhoea[a] |
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Endocrine system disorder (anti-androgenic effects[b,c], anti-glucocorticoid effects[b]) |

[a] May be observed at standard doses.

[b]Transient. Ketoconazole inhibits the conversion of cholesterol to steroid hormones such as testosterone and cortisol in a dose dependent and time-dependent manner.

[c] See also section *Special precautions for safe use in the target species* for effects in male breeding dogs.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

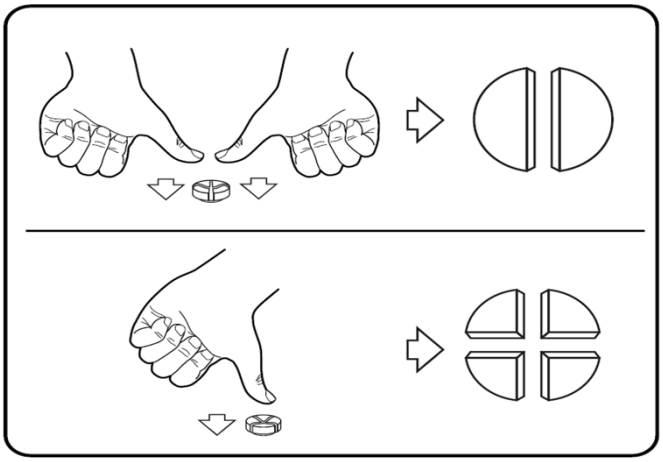
## 8. Dosage for each species, routes and method of administration

Oral use.
10 mg of ketoconazole per kg body weight daily, by oral administration. This corresponds to 1 tablet per 20 kg 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.

To ensure a correct dosage, body weight should be determined as accurately as possible.

## 9. Advice on correct administration

To be administered preferably together with food, in order to maximise absorption.
Tablets can be divided into 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.
Halves: With the tip of the thumbs, exert a slight vertical pressure on both sides of the tablet to break it into halves.
Quarters: With the tip of a thumb, exert a slight vertical pressure on the middle of the tablet to break it into quarters.



## 10. Withdrawal periods

Not applicable.

## 11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.
Shelf life of divided tablets: 3 days.

## 12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## 13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

## 14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 50406/4027

Aluminium - PVC/PE/PVDC blister.
Cardboard box of 1, 2, 3, 4, 5, 6, 7, 8, 9 or 10 blisters, containing 10 tablets each.

Not all pack sizes may be marketed.

## 15. PID LINK (Do not print heading)

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*
Find more product information by searching for the 'Product Information Database' on www.gov.uk.

## 16. Contact details

Marketing authorisation holder:
Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

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

Genera d.d.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

Local representatives and contact details to report suspected adverse reactions:,
Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel: +44 (0) 1939 211200

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

**17. Other information**

POM-V

*Gavin Hall*

Approved 01 May 2025