ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fungiconazol 200 mg tablets for dogs
Ketoconazole

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Ketoconazole 200 mg

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

10, 20, 30, 40, 50, 60, 70, 80, 90, 100 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 50406/4027

17. MANUFACTURER'S BATCH NUMBER

Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Alu/PVC/PE/PVDC blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fungiconazol 200 mg tablets for dogs
Ketoconazole

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot> {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Fungiconazol 200 mg tablets for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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 Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fungiconazol 200 mg tablets for dogs
Ketoconazole

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each tablet contains:
Active substance: Ketoconazole 200 mg

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

4. INDICATION(S)

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

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

In rare cases (more than 1 but less than 10 animals in 10,000 animals treated), 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 transient 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 section 12 for effects in male breeding dogs.
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 inform your veterinary surgeon Alternatively you can report via your national reporting system {national system details}

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

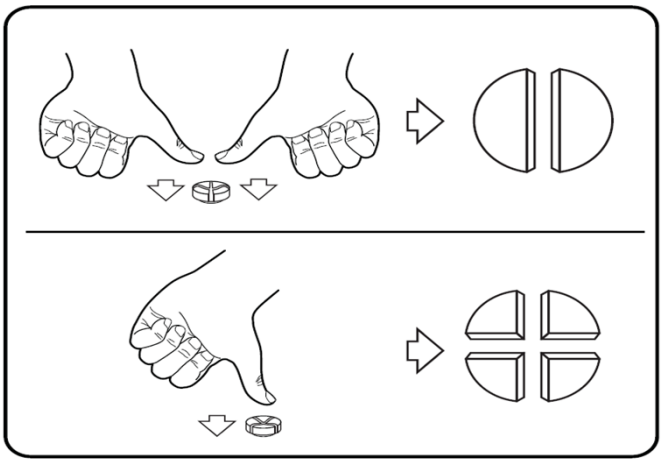
For oral use.
10 mg of ketoconazole per kg body weight daily, by oral administration. This corresponds to 1 tablet per 20 kg body weight daily.
It is recommended to sample the animal once a month during treatment and to stop antifungal administration after two negative cultures. When mycological follow 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.

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 PERIOD

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.
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.

12. SPECIAL WARNING(S)

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 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 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 product and these drugs should be avoided.
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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

May 2023

15. 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.

Approved 16 May 2023