# Fungiconazol 400 mg Tablets for Dogs

• Ketoconazole

# **Product identification**

### Medicine name: FUNGICONAZOL 400 MG TABLETS FOR DOGS Fungiconazol 400 mg Tablets for Dogs

## Active substance:

Ketoconazole

#### **Target species:**

Dog

### Route of administration:

Oral use

# **Product details**

#### Active substance and strength:

Ketoconazole 400.00 milligram(s) / 1.00 Tablet

#### Pharmaceutical form:

Tablet

#### Withdrawal period by route of administration:

#### Oral use:

Dog

### Anatomical therapeutic chemical veterinary (ATCvet) codes:

QJ02AB02

#### Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

#### Authorisation status:

Valid

#### Authorised in:

United Kingdom (Northern Ireland)

#### Package description:

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

# Additional information

#### **Entitlement type:**

Marketing Authorisation

#### Legal basis of product authorisation:

Hybrid application (Article 13(3) of Directive No 2001/82/EC)

#### Marketing authorisation holder:

Dechra Regulatory B.V.

#### Marketing authorisation date:

5/11/2014

#### Manufacturing sites for batch release:

Genera d.d. Lelypharma B.V.

#### **Responsible authority:**

The Veterinary Medicines Directorate

#### Authorisation number:

Vm 50406/4028

#### Date of authorisation status change:

5/11/2014

#### **Reference member state:**

France

#### **Procedure number:**

FR/V/0263/002

#### **Concerned member states:**

Austria Belgium Croatia Czechia Denmark Estonia Finland Greece Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg Netherlands Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to <u>www.adrreports.eu/vet</u>

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