Fungiconazol 400 mg Tablets for Dogs

Authorised

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:

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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 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 2 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 www.adrreports.eu/vet

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