Fungiconazol 400 mg tablets for dogs

Authorised

- Ketoconazole

Product identification

Medicine name:
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

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QJ02AB02

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Ireland

Available in:
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:

14/11/2014

Manufacturing sites for batch release:
Genera d.d.
Lelypharma B.V.

Responsible authority:
Health Products Regulatory Authority

Authorisation number:
VPA22622/047/002

Date of authorisation status change:
14/11/2014

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

Documents

Combined File of all Documents

eu-puar-frv0263002-mr-rpe965-en.pdf