

Robexera 5 mg chewable tablets for dogs

Authorised

- Robenacoxib

Product identification

Medicine name:

Robexera 5 mg chewable tablets for dogs
Robexera 5 mg kauwtabletten voor honden

Active substance:

Robenacoxib

Target species:

Dog

Route of administration:

Oral use

Product details

Active substance and strength:

Robenacoxib
5.00 milligram(s) / 1.00 Tablet

Pharmaceutical form:

Chewable tablet

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QM01AH91

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Netherlands

Package description:

OPA/Al/PVC/Aluminium perforated blister containing 10 tablets: 60 x 1 chewable tablet in perforated unit dose blisters, in a cardboard box.

OPA/Al/PVC/Aluminium perforated blister containing 10 tablets: 30 x 1 chewable tablet in perforated unit dose blisters, in a cardboard box.

OPA/Al/PVC/Aluminium perforated blister containing 10 tablets: 10 x 1 chewable tablet in perforated unit dose blisters, in a cardboard box.

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Generic application (Article 18 of Regulation (EU) 2019/6)

Marketing authorisation holder:

KRKA tovarna zdravil d.d. Novo mesto

Marketing authorisation date:

8/08/2023

Manufacturing sites for batch release:

TAD Pharma GmbH

Krka-Farma d.o.o.

KRKA tovarna zdravil d.d. Novo mesto

Responsible authority:

Medicines Evaluation Board

Authorisation number:

REG NL 130029

Date of authorisation status change:

6/09/2023

Reference member state:

Ireland

Procedure number:

IE/V/0775/001

Concerned member states:

Belgium Bulgaria Croatia Czechia Denmark Estonia Finland France
Germany Hungary Italy Latvia Lithuania Netherlands Norway Poland
Portugal Romania Slovakia Slovenia Spain Sweden
United Kingdom (Northern Ireland)

Generic of:

600000004401

600000004401

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

Documents

Combined File of all Documents

English (PDF)

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Summary of Product Characteristics

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