Robexera 10 mg chewable tablets for dogs

• Robenacoxib

Product identification

Medicine name:

Robexera 10 mg chewable tablets for dogs Robexera 10 mg таблетки за дъвчене за кучета

Active substance:

Robenacoxib

Target species:

Dog

Route of administration:

Oral use

Product details

Active substance and strength:

Robenacoxib 10.00 milligram(s) / 1.00 Tablet

Pharmaceutical form:

Chewable tablet

Withdrawal period by route of administration:

Oral use:

Dog

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QM01AH91

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Bulgaria

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/AI/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:

20/06/2023

Manufacturing sites for batch release:

Krka-Farma d.o.o. TAD Pharma GmbH KRKA tovarna zdravil d.d. Novo mesto

Responsible authority:

Bulgarian Food Safety Authority

Authorisation number: 0022-3191

Date of authorisation status change: 20/06/2023

Reference member state:

Ireland

Procedure number:

IE/V/0775/002

Concerned member states:

Belgium Bulgaria Croatia Czechia Estonia Finland France Germany Hungary Italy Latvia Lithuania 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>

Documents

Summary of Product Characteristics

English (PDF) Published on: 3/05/2024 Package Leaflet

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Labelling

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