Source URL: https://medicines.health.europa.eu/veterinary/en/600000991451

Robexera 40 mg chewable tablets for dogs

Authorised

Robenacoxib

Product identification

Medicine name:

Robexera 40 mg chewable tablets for dogs ROBEXERA 40 MG COMPRIMES A CROQUER POUR CHIENS

Active substance:

Robenacoxib

Target species:

Dog

Route of administration:

Oral use

Product details

Active substance and strength:

Robenacoxib 40.00 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:

France

Package description:

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

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

OPA/Al/PVC/Aluminium perforated blister containing 10 tablets: 10×1 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:

20/07/2023

Manufacturing sites for batch release:

TAD Pharma GmbH

Krka-Farma d.o.o.

KRKA tovarna zdravil d.d. Novo mesto

Responsible authority: French Agency For Food, Environmental And Occupational Health & Safety
Authorisation number: FR/V/2166712 9/2023
Date of authorisation status change: 20/07/2023
Reference member state: Ireland
Procedure number: IE/V/0775/004
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: 60000004401 60000004401
To consult adverse reactions on veterinary medicinal products please go to

www.adrreports.eu/vet

Documents

Summary of Product Characteristics

Package Leaflet and Labelling
This document does not exist in this language (English). You can find it in another language below.
Combined File of all Documents
ie-puar-mr-iev0775004-robexera-40-mg-chewable-tablets-for-dogs-en.pdf