

Robexera 5 mg chewable tablets for dogs

Authorised

- Robenacoxib

Product identification

Medicine name:

Robexera 5 mg chewable tablets for dogs

Robexera Vet. 5 mg tyggetabletter

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:

Denmark

Package description:

OPA/AI/PVC/Aluminium perforated blister containing 10 tablets: 10 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/AI/PVC/Aluminium perforated blister containing 10 tablets: 60 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:

7/02/2025

Manufacturing sites for batch release:

TAD Pharma GmbH

Krka-Farma d.o.o.

KRKA tovarna zdravil d.d. Novo mesto

Responsible authority:

Danish Medicines Agency

Authorisation number:

72503

Date of authorisation status change:

7/02/2025

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)

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

Documents

Combined File of all Documents

Summary of Product Characteristics

ie-puar-mr-iev0775001-robexera-5-mg-chewable-tablets-for-dogs-en.pdf