

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

{CARDBOARD BOX}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Robexera 6 mg chewable tablets

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each tablet contains 6 mg robenacoxib.

**3. PACKAGE SIZE**

6 tablets  
10 tablets  
30 tablets  
60 tablets

**4. TARGET SPECIES**

Cats

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Oral use.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

**9. SPECIAL STORAGE PRECAUTIONS**

Do not store above 30 °C. Store in the original package in order to protect from moisture.

**10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"**

Read the package leaflet before use.

**11. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

KRKA, d.d., Novo mesto

**14. MARKETING AUTHORISATION NUMBERS**

Vm 01656/3121

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

{BLISTER}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Robexera



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

6 mg

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

## **B. PACKAGE LEAFLET**

## **PACKAGE LEAFLET**

### **1. Name of the veterinary medicinal product**

Robexera 6 mg chewable tablets for cats

### **2. Composition**

Each chewable tablet contains:

#### **Active substance:**

Robenacoxib 6 mg

Light brown, round, biconvex tablets with lighter and darker dots.

### **3. Target species**

Cats.



### **4. Indications for use**

For the treatment of pain and inflammation associated with acute and chronic musculoskeletal disorders.

For the reduction of moderate pain and inflammation associated with orthopaedic surgery.

### **5. Contraindications**

Do not use in cats suffering from ulceration in the digestive tract.

Do not use together with non-steroidal anti-inflammatory drugs (NSAIDs) or corticosteroids, medicines commonly used in the treatment of pain, inflammation and allergies.

Do not use in case of hypersensitivity to robenacoxib or to any of the constituents of the tablets.

Do not use in pregnant or lactating cats or cats used for breeding because the safety of this product has not been established in these animals.

### **6. Special warnings**

#### Special precautions for safe use in the target species:

The safety of this veterinary medicinal product has not been established in cats weighing less than 2.5 kg or under 4 months of age.

Use in cats with impaired function of the heart, kidneys or liver or in cats that are dehydrated, have low volume of circulating blood or have low blood pressure may involve additional risks. If use cannot be avoided, these cats require careful monitoring.

Response to long-term treatment should be monitored at regular intervals by a veterinary surgeon.

Clinical field studies showed that robenacoxib was well-tolerated by most cats for up to 12 weeks.

Use this veterinary medicinal product under strict veterinary monitoring in cats at risk of stomach ulcer or if the animal previously displayed intolerance to other NSAIDs.

Tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

For pregnant women, particularly near-term pregnant women, prolonged dermal exposure increases the risk of premature closure of the ductus arteriosus in the foetus. Pregnant women should take special care to avoid accidental exposure. Accidental ingestion increases the risk for NSAID adverse effects, particularly in small children. Care should be taken to avoid accidental ingestion by children. In order to prevent children from accessing the product, do not remove tablets from the blister until ready to administer to the animal.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use of the veterinary medicinal product.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use during pregnancy and lactation.

Fertility:

The safety of the veterinary medicinal product has not been established in cats used for breeding. Do not use in breeding animals.

Interaction with other medicinal products and other forms of interaction:

This veterinary medicinal product must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Pre-treatment with other anti-inflammatory medicines may result in additional or increased adverse effects and a treatment-free period with such substances should be observed for at least 24 hours before the commencement of treatment with this veterinary medicinal product. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

Concomitant treatment with medicines displaying action on renal flow, e.g. diuretics or angiotensin-converting enzyme (ACE) inhibitors, should be subject to clinical monitoring.

In healthy cats treated with or without the diuretic furosemide, concomitant administration of this veterinary medicinal product with the ACE inhibitor benazepril for 7 days was not associated with any negative effects on plasma aldosterone concentrations, plasma renin activity or glomerular filtration rate. No safety data in the target population and no efficacy data in general exist for the combined treatment of robenacoxib and benazepril.

As anaesthetics may affect the blood flow through the kidneys (renal perfusion), the use of parenteral fluid therapy during surgery should be considered to decrease potential renal complications when using NSAIDs peri-operatively.

Concurrent administration of potentially nephrotoxic medicines should be avoided as there might be an increased risk of renal toxicity.

Concurrent use of other active substances that have a high degree of protein binding may compete with robenacoxib for binding and thus lead to toxic effects.

#### Overdose:

In healthy young cats aged 7-8 months, oral robenacoxib administered at high overdoses (4, 12 or 20 mg/kg/day for 6 weeks) did not produce any signs of toxicity, including no evidence of any gastrointestinal, kidney or liver toxicity and no effect on bleeding time.

In healthy young cats aged 7-8 months, oral robenacoxib administered at overdoses of up to 5 times the maximum recommended dose (2.4 mg, 7.2 mg, 12 mg robenacoxib/kg bodyweight) for 6 months was well tolerated. A reduction in body weight gain was observed in treated animals. In the high dose group kidney weights were decreased and sporadically associated with renal tubular degeneration/regeneration but not correlated with evidence of renal dysfunction on clinical pathology parameters (laboratory test results).

The interchangeable use of veterinary medicinal products containing robenacoxib in the form of tablets and solution for injection in 4-month-old cats at overdoses of up to 3 times the maximum recommended dose (2.4, 4.8 and 7.2 mg robenacoxib/kg orally and 2.0 mg, 4.0 mg and 6.0 mg robenacoxib/kg subcutaneously) resulted in a dose-dependent increase of sporadic oedema at the injection site and minimal to mild subacute/chronic inflammation of the subcutaneous tissue. A dose-dependent increase in the QT interval (an effect on the electric signals in the heart, seen on EKG), a decreased heart rate and corresponding increased respiratory rate were observed in laboratory studies. No relevant effects on body weight, bleeding time or evidence of any gastrointestinal, kidney or liver toxicity were observed.

In overdose studies conducted in cats, there was a dose-dependent increase in the QT interval. The biological relevance of increased QT intervals outside of normal variations observed following overdose of robenacoxib is unknown. No changes in the QT interval were observed after a single intravenous administration of 2 or 4 mg/kg robenacoxib to anaesthetised healthy cats.

As with any NSAID, overdose may cause gastrointestinal, kidney, or liver toxicity in sensitive or compromised cats. There is no specific antidote. Symptomatic, supportive therapy is recommended and should consist of administration of gastrointestinal protective agents and infusion of isotonic saline.

## 7. Adverse events

Cats:

Common (1 to 10 animals / 100 animals treated):	Diarrhoea <sup>1</sup> , Vomiting <sup>1</sup>
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Elevated renal parameters (creatinine, BUN, and SDMA) <sup>2</sup> Renal insufficiency <sup>2</sup> Lethargy

<sup>1</sup>Mild and transient.

<sup>2</sup>More commonly in older cats and with concomitant use of anaesthetic or sedative agents.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

## 8. Dosage for each species, routes and method of administration

Oral use.

The recommended dose of robenacoxib is 1 mg/kg body weight with a range 1-2.4 mg/kg. The following number of tablets should be given once daily at the same time every day.

Body weight (kg)	Number of tablets
2.5 to < 6	1 tablet
6 to 12	2 tablets

**Acute musculoskeletal disorders:** treat for up to 6 days.

**Chronic musculoskeletal disorders:** Duration of treatment should be decided by the responsible veterinarian on an individual basis.

A clinical response is normally seen within 3-6 weeks. Treatment should be discontinued after 6 weeks if no clinical improvement is apparent.

**Orthopaedic surgery:** Give as a single oral treatment prior to orthopaedic surgery. Premedication should only be carried out in combination with butorphanol-analgesia. The tablet(s) should be administered without food at least 30 minutes prior to surgery.

After surgery, once daily treatment may be continued for up to two further days. If necessary, additional analgesic treatment with opioids is recommended.

The interchangeable use of the veterinary medicinal product in the form of tablets and solution for injection has been tested in a target animal safety study and was shown to be well tolerated by the cats.

For cats, the veterinary medicinal products containing robenacoxib in the form of solution for injection or tablets may be used interchangeably in accordance with the indications and directions of use approved for each pharmaceutical form. Treatment should not exceed one dose (either tablet or injection) per day. Please note that the recommended doses for the two formulations may be different.

#### **9. Advice on correct administration**

Give either without food or with a small amount of food. The tablets should not be divided or broken.

#### **10. Withdrawal periods**

Not applicable.

#### **11. Special storage precautions**

Keep out of the sight and reach of children.

Do not store above 30 °C. Store in the original package in order to protect from moisture.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the blister after Exp. The expiry date refers to the last day of that month.

#### **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

#### **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

#### **14. Marketing authorisation numbers and pack sizes**

Vm 01656/3121

OPA/Al/PVC/Aluminium blisters containing 6 or 10 tablets.

Pack sizes:

Cardboard box with 1 blister of 6 tablets (6 tablets).

Cardboard box with 1 blister of 10 tablets (10 tablets).

Cardboard box with 3 blisters of 10 tablets (30 tablets).

Cardboard box with 6 blisters of 10 tablets (60 tablets).

Not all pack sizes may be marketed.

#### **15. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

#### **16. Contact details**

Marketing authorisation holder and contact details to report suspected adverse reactions:

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer responsible for batch release:

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

KRKA-FARMA d.o.o., V. Holjevca 20/E, Jastrebarsko, 10450, Croatia

TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

#### **17. Other information**

POM-V

*Gavin Hall*

Approved: 06 January 2026