# 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 20 mg chewable tablets

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains 20 mg robenacoxib.

## 3. PACKAGE SIZE

10 x 1 tablet
30 x 1 tablet
60 x 1 tablet

## 4. TARGET SPECIES

Dogs

## 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

## 14. MARKETING AUTHORISATION NUMBERS

Vm 01656/3031

## 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

20 mg

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}

KRKA

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Robexera 5 mg chewable tablets for dogs

Robexera 10 mg chewable tablets for dogs

Robexera 20 mg chewable tablets for dogs

Robexera 40 mg chewable tablets for dogs

## 2. Composition

Each chewable tablet contains:

**Active substance:**
Robenacoxib:
5 mg
10 mg
20 mg
40 mg

Light brown, round, biconvex tablets with lighter and darker dots and marked on one side of the tablet:
5 mg: T1
10 mg: T2
20 mg: T3
40 mg: T4

## 3. Target species

Dogs.

## 4. Indications for use

For the treatment of pain and inflammation of chronic osteoarthritis.
For the treatment of pain and inflammation associated with soft tissue surgery.

## 5. Contraindications

Do not use in dogs suffering from stomach ulcers or with liver disease.
Do not use together with other non-steroidal anti-inflammatory drugs (NSAIDs) or corticosteroids, medicines commonly used in the treatment of pain, inflammation and allergies.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in pregnant or lactating bitches (see section Special warnings).

## 6. Special warnings

Special precautions for safe use in the target species:
In clinical studies in dogs with osteoarthritis, inadequate response to treatment was seen in 10–15% of the dogs.

The safety of this veterinary medicinal product has not been established in dogs weighing less than 2.5 kg or under 3 months of age.

For long term therapy, liver enzymes should be monitored at the start of therapy, e.g. after 2, 4 and 8 weeks. Thereafter it is recommended to continue regular monitoring, e.g. every 3–6 months. Therapy should be discontinued if liver enzyme activities increase markedly or the dog shows symptoms such as anorexia, apathy or vomiting in combination with elevated liver enzymes.

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

Use this veterinary medicinal product under strict veterinary monitoring in dogs 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. Tablets should be administered and stored (in the original packaging) out of sight and reach of children.

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:
Do not use in breeding animals.

Interaction with other medicinal products and other forms of interaction:
Robenacoxib must not be administered in conjunction with other NSAIDs or glucocorticoids. Pre-treatment with other anti-inflammatory medicines may result in additional or increased adverse effects and accordingly a treatment-free period with such substances should be observed for at least 24 hours before the commencement of treatment with robenacoxib. 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 dogs treated with and without the diuretic furosemide, concomitant administration of robenacoxib with the ACE inhibitor benazepril for 7 days was not associated with any negative effects on urine 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.

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 dogs aged 5–6 months, oral robenacoxib administered at high overdoses (4, 6 or 10 mg/kg/day for 6 months) did not produce any signs of toxicity, including no evidence of any gastrointestinal, kidney or liver toxicity and no effect on bleeding time. Robenacoxib also had no detrimental effects on cartilages or joints.

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

The use of robenacoxib tablets in mongrel dogs at overdoses of up to 3 times the maximum recommended dose (2.0, 4.0 and 6.0 plus 4.0, 8.0 and 12.0 mg robenacoxib/kg orally) resulted in inflammation, congestion or haemorrhage in the duodenum, jejunum and caecum. No relevant effects on body weight, bleeding time or evidence of any kidney or liver toxicity were observed.

## 7. Adverse events

Dogs:

| | |
|---|---|
| Very common<br>(>1 animal / 10 animals treated): | Gastrointestinal adverse events.[1]<br>Vomiting, loose stool.[1] |
| Common<br>(1 to 10 animals / 100 animals treated): | Decreased appetite.[1]<br>Diarrhoea.[1]<br>Elevated liver enzymes.[2] |

| | |
|---|---|
| Uncommon<br>(1 to 10 animals / 1,000 animals treated): | Blood in faeces[1], vomiting[3].<br>Anorexia, apathy.[3] |
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Lethargy. |

[1] Most cases were mild and recovered without treatment.
[2] In dogs treated up to 2 weeks no increases in liver enzyme activities were observed. However, with long-term treatment, increases in liver enzyme activities were common. In most cases there were no clinical signs and the liver enzyme activities either stabilised or decreased with continued treatment.
[3] Clinical signs associated with increases in liver enzyme activities.

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 using the contact details at the end of this leaflet, or via your national reporting system {https://www.gov.uk/report-veterinary-medicine-problem}.

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

Oral use.
**Osteoarthritis:** The recommended dose of robenacoxib is 1 mg/kg body weight with a range 1–2 mg/kg. Administer once daily at the same time every day according to the table below.

**Number of Tablets by Strength and Body Weight for Osteoarthritis**

| Body Weight (kg) | Number of Tablets by Strength | | | |
|---|---|---|---|---|
| | 5 mg | 10 mg | 20 mg | 40 mg |
| 2.5 to < 5 | 1 tablet | | | |
| 5 to < 10 | | 1 tablet | | |
| 10 to < 20 | | | 1 tablet | |
| 20 to < 40 | | | | 1 tablet |
| 40 to 80 | | | | 2 tablets |

A clinical response is normally seen within a week. Treatment should be discontinued after 10 days if no clinical improvement is apparent.

For long-term treatment, once a clinical response has been observed, the dose of robenacoxib can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic osteoarthritis may vary over time. Regular monitoring should be undertaken by the veterinarian.

**Soft tissue surgery:** The recommended dose of robenacoxib is 2 mg/kg body weight with a range of 2-4 mg/kg. Give as a single oral treatment prior to soft tissue surgery.
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.

**Number of Tablets by Strength and Body Weight for Soft Tissue Surgery**

| Body Weight (kg) | Number of Tablets by Strength | | | |
|---|---|---|---|---|
| | 5 mg | 10 mg | 20 mg | 40 mg |
| 2.5 | 1 tablet | | | |
| > 2.5 to < 5 | | 1 tablet | | |
| 5 to < 10 | | | 1 tablet | |
| 10 to < 20 | | | | 1 tablet |
| 20 to < 40 | | | | 2 tablets |
| 40 to < 60 | | | | 3 tablets |
| 60 to 80 | | | | 4 tablets |

## 9. Advice on correct administration

Do not administer with food since clinical trials demonstrated better efficacy of robenacoxib for osteoarthritis when administered without food or at least 30 minutes before or after a meal. Soft Tissue Surgery: Administer the first dose at least 30 minutes prior to surgery. Tablets are flavoured. 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. The expiry date refers to the last day of that month.

## 12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
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

*Robexera 5 mg Chewable Tablets for Dogs: Vm 01656/3029*
*Robexera 10 mg Chewable Tablets for Dogs: Vm 01656/3030*
*Robexera 20 mg Chewable Tablets for Dogs: Vm 01656/3031*
*Robexera 40 mg Chewable Tablets for Dogs: Vm 01656/3032*

OPA/Al/PVC/Aluminium perforated blister containing 10 tablets: 10 x 1, 30 x 1 or 60 x 1 chewable tablet in perforated unit dose blisters, in a cardboard box.

Not all pack sizes may be marketed.

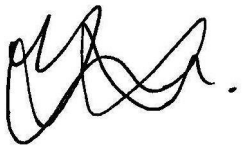
## 15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

## 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



Approved: 07 August 2023