1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rogiola 5 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substance:
Robenacoxib 5 mg

Excipients:

Qualitative composition of excipients and other constituents
Cellulose, microcrystalline
Povidone
Crospovidone
Yeast powder
Meat flavour
Silica, colloidal anhydrous
Magnesium stearate

Light brown, round, biconvex tablets with lighter and darker dots and marked with T1 on one side of the tablet.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use in dogs suffering from gastrointestinal ulceration or with hepatic disease.
Do not use concomitantly with corticosteroids or other non-steroidal anti-inflammatory drugs (NSAIDs).
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in pregnant and lactating animals (see section 3.7).

3.4 Special warnings

In clinical studies in dogs with osteoarthritis, inadequate response to treatment was seen in 10-15% of the dogs.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The safety of the 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 clinical signs such as anorexia, apathy or vomiting in combination with elevated liver enzymes.

Use in dogs with impaired cardiac or renal function or dogs that are dehydrated, hypovolaemic or hypotensive may involve additional risks. If use cannot be avoided, these dogs require careful monitoring.

Use this product under strict veterinary monitoring in dogs with a risk of gastrointestinal ulcers, or if the dog 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Gastrointestinal adverse events.[1] Vomiting, loose stool.[1]
Common (1 to 10 animals / 100 animals treated):	Decreased appetite.[1] Diarrhoea.[1] Elevated liver enzymes.[2]
Uncommon	Blood in faeces[1], vomiting[3].

(1 to 10 animals / 1,000 animals treated):	Anorexia, apathy.[3]
Very rare (<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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

Pregnancy and lactation:
Do not use during pregnancy and lactation.

Fertility:
Do not use in breeding animals

3.8 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.

3.9 Administration routes and dosage

For oral use.

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.

Tablets are flavoured. The tablets should not be divided or broken.

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QM01AH91.

4.2 Pharmacodynamics

Robenacoxib is a non-steroidal anti-inflammatory drug (NSAID) of the coxib class. It is a potent and selective inhibitor of the cyclooxygenase 2 enzyme (COX-2). The cyclooxygenase enzyme (COX) is present in two forms. COX-1 is the constitutive form of the enzyme and has protective functions, e.g. in the gastrointestinal tract and kidneys. COX-2 is the inducible form of the enzyme and is responsible for the production of mediators including PGE_2 which induce pain, inflammation or fever.

In an *in vitro* whole blood assay in dogs, robenacoxib was approximately 140 fold selective for COX-2 (IC_{50} 0.04 μM) as compared to COX-1 (IC_{50} 7.9 μM). Robenacoxib produced marked inhibition of COX-2 activity and had no effect on COX-1 activity in dogs at oral doses ranging from 0.5 to 4 mg/kg. Robenacoxib tablets are therefore COX-1 sparing at recommended doses in dogs. Robenacoxib had analgesic and anti-inflammatory actions in an inflammation model in dogs with single oral doses ranging from 0.5 to 8 mg/kg, with an ID_{50} of 0.8 mg/kg and a rapid onset of action (0.5 h). In clinical trials in dogs, robenacoxib reduced the lameness and inflammation associated with chronic osteoarthritis, and pain, inflammation and the need for rescue treatment in dogs undergoing soft tissue surgery.

4.3 Pharmacokinetics

After oral administration of robenacoxib flavoured tablets at 1-2 mg/kg without food, peak blood concentrations are attained rapidly with a T_{max} of 0.75 h, a C_{max} of 2180 ng/ml and an AUC_i of 2007 ng·h/ml. Co-administration of robenacoxib non-flavoured tablets with food produced no delay in T_{max}, but slightly lower values for C_{max} and AUC. The systemic bioavailability of robenacoxib tablets in dogs was 62% with food and 84% without food.

Robenacoxib has a relatively small volume of distribution (Vss 240 ml/kg) and is highly bound to plasma proteins (>99%).

Robenacoxib is extensively metabolised by the liver in dogs. Apart from one lactam metabolite, the identity of other metabolites is not known in dogs.

Robenacoxib is cleared rapidly from blood (CL 0.81 L/kg/h) with an elimination $t_{1/2}$ of 0.7 h after intravenous administration. After oral administration of the tablets, the terminal half-life in blood was 0.91 h. Robenacoxib persists longer and at higher concentrations at sites of inflammation than in blood. Robenacoxib is excreted predominantly via the biliary route (~65%) and the remainder via the kidneys. Repeated oral administration of robenacoxib to dogs at dosages of 2-10 mg/kg for 6 months produced no change in the blood profile, with neither accumulation of robenacoxib nor enzyme

induction. Accumulation of metabolites has not been tested. The pharmacokinetics of robenacoxib do not differ between male and female dogs, and are linear over the range 0.5-8 mg/kg.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Krka, d.d., Novo mesto

7. MARKETING AUTHORISATION NUMBER(S)

VPA10774/076/001

8. DATE OF FIRST AUTHORISATION

21/08/2023

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

16/04/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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