# Robexera®

## ROBENACOXIB FOR DOGS

**For the treatment of pain and inflammation in dogs associated with chronic osteoarthritis, orthopaedic or soft tissue surgery, and during the perioperative period.[1,2]**

The 1st Robenacoxib generic to market, providing practices and clients with an affordable solution for pain and inflammation, including OA. The injection and tablets can be used interchangeably[2,9] and and the tablets with meat and yeast flavouring support ease of administration.[1]


**PRESENTATIONS**
Injection
Tablets

**PACK SIZE**
Injection: 20ml vial
Tablets: 30 per pack

**CATEGORY**
POM-V

**TARGET SPECIES**
Dogs
*For Robexera Cat range refer to separate detailer.*

# Robexera®

*Robenacoxib*

## Pain management at every step

Robenacoxib is the only highly COX2 selective injectable NSAID for dogs and can be used throughout the perioperative period for the treatment of pain and inflammation associated with orthopaedic or soft tissue surgery.[2] The chewable format of the tablets aids successful transition to at home care, with combined flavouring of yeast and hydrolyzed vegetable meat protein (meat flavour) to aid administration.[1]

Krka's comprehensive NSAID portfolio gives veterinary practices the flexibility to offer cost-effective pain management solutions for dogs, both in the perioperative setting and for long-term osteoarthritis (OA) care.

Backed by Krka's commitment to proven efficacy, Robexera further expands the range of NSAID options available, supporting tailored treatment choices to meet the needs of both veterinarians and pet owners.

### Injection


1st generic to market improving affordability for practices and clients


Bioequivalent to originator product[3]


In clinical trials, robenacoxib reduced pain and inflammation in dogs undergoing orthopaedic or soft tissue surgery[2]


Reduced the need for rescue treatment in dogs undergoing soft tissue surgery[2]

### Tablets


1st generic to market improving affordability for practices and clients


Bioequivalent to originator product[14]


Supporting ease of administration, Robexera tablets are flavoured with yeast and artificial meat extract.


Provided in 4 strengths with colour-coded boxes and fully perforated blisters, along with a set of PIL sheets per pack that covert to prescribing envelopes.

## From practice to home with ease

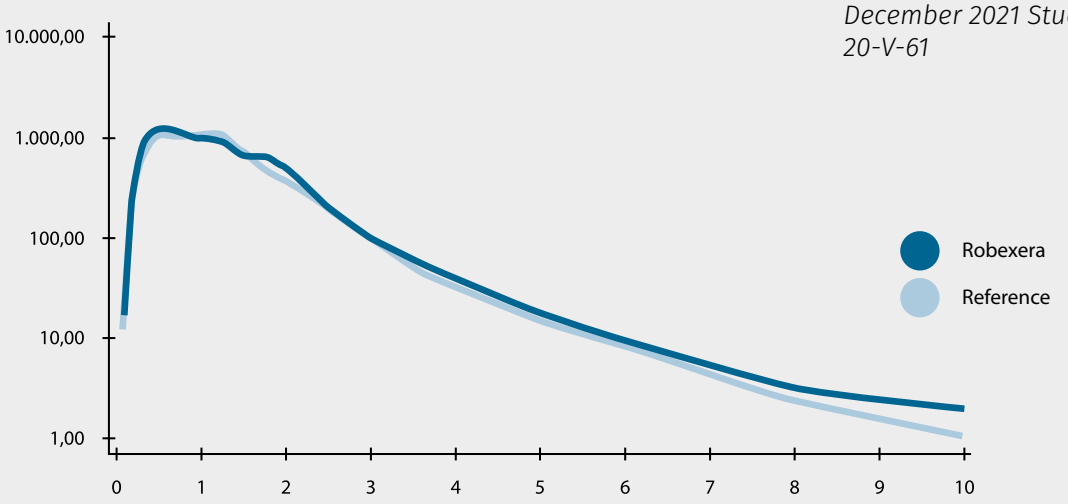
Robexera injection also offers interchangeable[9] use with tablet formulations, and this process is well tolerated in dogs,[1,11] enabling easy transition to post-surgery care by pet owners at home.

# Robexera is bioequivalent to the originator product[14]

**Comparison of mean plasma profiles (Log-Linear) of robenacoxib for dogs after administration of the test product robenacoxib Krka Robexera 20 mg tablets and the reference product tablets 20 mg.**

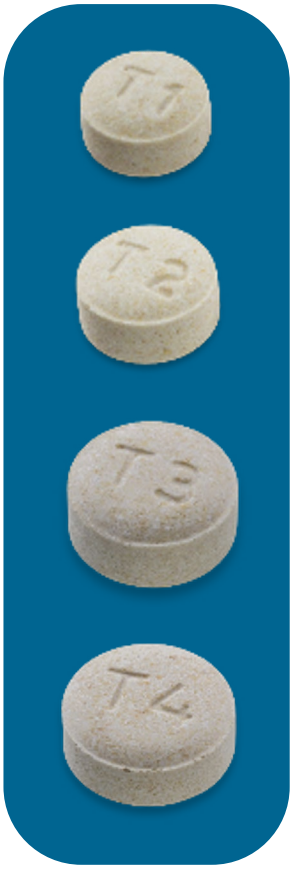
*MEAN PLASMA CURVES: Plasma Robenacoxib concentrations (ng/mL) – Log Linear plot*

*December 2021 Study Code: 20-V-61*




# Robexera Chewable tablet has been formulated to aid administration

The tablets are available in four strengths with colour coded boxes and are provided with perforated blisters and combined PIL sheet envelopes. To aid administration, the tablets contain two palatability components - yeast and hydrolyzed vegetable protein (meat flavour) - as part of its chewable formulation.



**Size**

5mg – approx. 6mm diameter
10mg – approx. 7mm diameter
20mg – approx. 9mm diameter
40mg – approx. 12mm diameter

**Flavours**

Yeast powder and artificial meat flavouring

# Robexera (robenacoxib) differs from other NSAIDs

Designed to concentrate at the inflammation site[8]

24hrs efficacy in the area with inflammatory exudates[9]

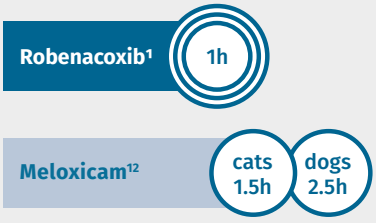
Fast onset: COX-2 inhibition within the first hour[1]

Built for longer-term use. Provides a fast onset of action and rapid elimination of excess from the blood.[1]

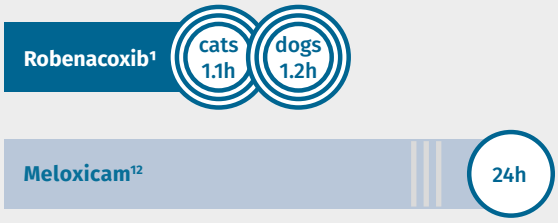
# Fast onset of action, low volume of distribution and rapid elimination of excess from blood and well perfused organs[8] reduce wider systemic impact

## Comparison of robenacoxib and meloxicam NSAID injectables

**Time to reach Max Plasma**

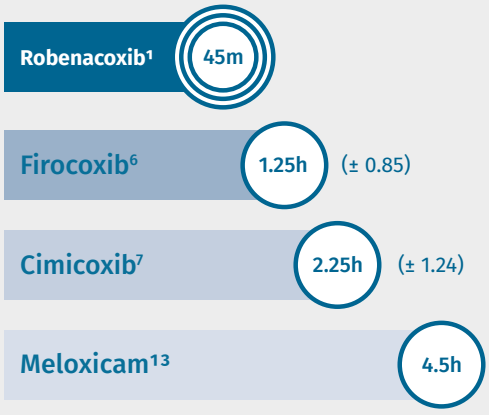



**Elimination subcutaneous**

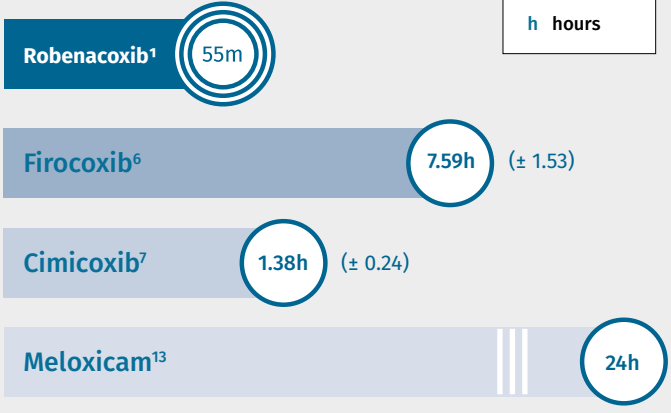



## Comparison of robenacoxib and other NSAID tablets

Time to reach max. plasma concentration ($T_{max}$)




Elimination time ($T_{1/2}$)




m minutes
h hours

# Focus areas in clinical practice

**Pre surgery:**
Targeted inflammation reduction

**Post surgery:**
Fast acting and targeted pain relief

**Osteoarthritis care:**
Targeted 24 hour pain relief

Simple once a day dosing regime

Reduced systemic impact

| Once a day | Right where it hurts | Precise action |
|---|---|---|
| Robenacoxib persists at the inflammation site, providing effective 24-hour pain relief.[8,9] | Targeted action: Robenacoxib reaches peak concentration and persists longer at the inflamation site than in the blood due to preferential distribution into inflammatory joint synovial fluid.[8,9] | Tissue selectivity: Due to short half-life, high ability for protein binding, and its carboxylic acid group, it is rapidly eliminated from the bloodstream and spares well-perfused organs, e.g. kidneys, liver, and GI tract[9] and has no impact on joint cartilage.[5] |

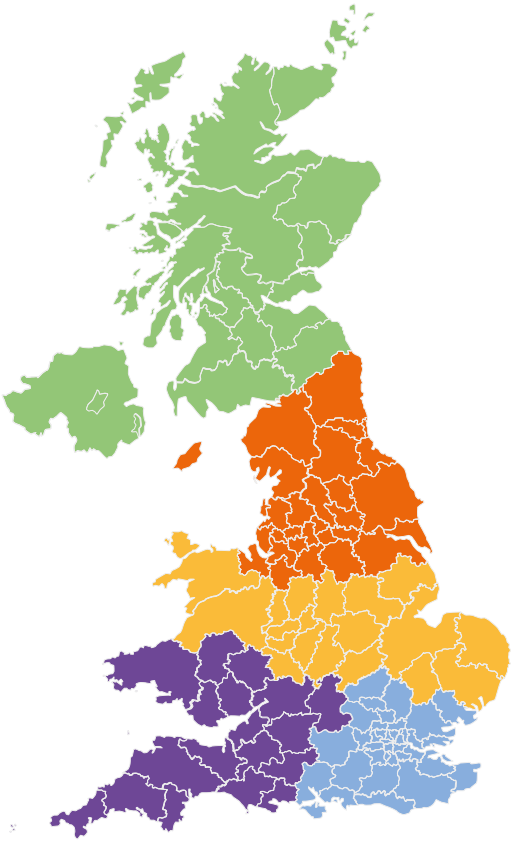
# Dosage and administration

| Product | Strengths | Pack Size | Administration |
|---|---|---|---|
| Robexera Chewable Tablets | 5mg<br>10mg<br>20mg<br>40mg | 30 Tablets | For oral use. Give either without food or with a small amount of food. The tablets should not be divided or broken.<br>The recommended dose of robenacoxib is 1 mg/kg for OA and 2mg/kg for soft tissue surgery – see SPC and Datasheet for more information.<br>Licensed in Dogs between 2.5 – 80kg bodyweight and minimum 3 months of age. Tablets should be given once daily at the same time every day. |


| Product | Strength | Pack Size | Administration |
|---|---|---|---|
| Robexera Solution for Injection | 20mg/ml | 20ml | 2 mg robenacoxib/kg body weight (1ml of the veterinary medicinal product per 10 kg body weight) from 2 months of age and >2.5kg<br>To be administered by single subcutaneous (s.c.) injection.<br>Administer the veterinary medicinal product approximately 30 minutes before the start of surgery, for example around the time of induction of general anaesthesia.<br>After soft tissue surgery in dogs, once daily treatment may be continued at the same dosage and at the same time every day for up to 2 days.<br>The interchangeable use of the veterinary medicinal products containing robenacoxib in the form of tablets and solution for injection has been tested in target animal safety studies and was shown to be well tolerated by dogs. |


See further information in the summary SPC for dog tablets and injection at the end of this detailer.

# KRKA UK SALES REGIONS



TO CONTACT YOUR KRKA REGIONAL ACCOUNT MANAGER - SCAN HERE

**SCOTLAND & NORTHERN IRELAND**

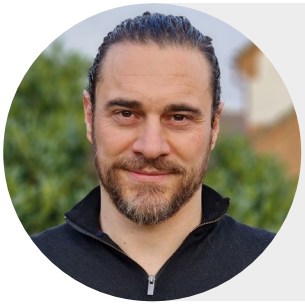
**NORTH**

**CENTRAL**

**SOUTH EAST**

**SOUTH WEST**

# VETERINARY SUPPORT



TECHNICAL VET

**Renzo Di Florio**

TEL 07756 29434
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CAN PROVIDE TECHNICAL SUPPORT WITH:

- Workshops
- Clinical support
- Pharmacovigilance
- Technical advice and content

# Datasheet information

## Robexera 5 mg, 10 mg, 20 mg, 40 mg chewable tablets for dogs

***This product is also indicated for Cats, please refer to Krka Robexera Cat Detailer for SPC summary information for cats.***

**PRESENTATION**
Chewable tablets. Light brown, round, biconvex tablets with possible lighter and darker dots and marked with T1 on one side of the tablet. Robexera 5 mg chewable tablets for dogs contains 5 mg robenacoxib, Robexera 10 mg chewable tablets for dogs: contains 10 mg robenacoxib, Robexera 20 mg chewable tablets for dogs: contains 20 mg robenacoxib, Robexera 40 mg chewable tablets for dogs: contains 40 mg robenacoxib.

**EXCIPIENTS**
Cellulose, microcrystalline, povidone, crospovidone, yeast powder, meat flavour, colloidal anhydrous silica and magnesium stearate.

**USES**
For the treatment of pain and inflammation associated with chronic osteoarthritis in dogs. For the treatment of pain and inflammation associated with soft tissue surgery in dogs.

**DOSAGE AND ADMINISTRATION**
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 on the right.

*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, according to the table on the right. 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 |

**USE DURING PREGNANCY AND LACTATION:**
Do not use in pregnant or lactating dogs because the safety of robenacoxib has not been established during pregnancy and lactation or in dogs used for breeding. Fertility, do not use in breeding animals.

**CONTRAINDICATIONS, WARNINGS ETC:**
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 case of hypersensitivity to the active substance or to any of the excipients. In clinical studies in dogs with osteoarthritis, inadequate response to treatment was seen in 10-15% of the dogs.

**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 accidental ingestion, store tablets out of the reach of 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. 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.

**ADVERSE EVENTS**
Gastrointestinal adverse events – vomiting and soft faeces - were reported very commonly, but most cases were mild and recovered without treatment. Decreased appetite and diarrhoea were reported commonly. In dogs treated for 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. Blood in the faeces was reported uncommonly. Increases in liver enzyme activities associated with clinical signs of anorexia, apathy or vomiting were uncommon. Lethargy may be observed very rarely.

**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.

**INTERACTIONS**
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.

**ENVIRONMENTAL SAFETY**
Medicines should not be disposed of via wastewater.

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

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

**PACKAGING**
Aluminium (OPA/Al/PVC)/ Aluminium perforated blister: 10, 30 or 60 chewable tablets, in a box.
Not all pack sizes may be marketed.

**LEGAL CATEGORY**
POM-V

**MARKETING AUTHORISATION NUMBERS**
Robexera 5 mg chewable tablets for dogs
Vm 01656/5029
Robexera 10 mg chewable tablets for dogs
Vm 01656/5030
Robexera 20 mg chewable tablets for dogs
Vm 01656/5031
Robexera 40 mg chewable tablets for dogs
Vm 01656/5032

# Datasheet information

## Robexera 20 mg/ml solution for injection for dogs

***This product is also indicated for Cats, please refer to Krka Robexera Cat Detailer for SPC summary information for cats.***

**PRESENTATION**

Clear, colourless to slightly brownish-yellow solution

**QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each ml contains: Active substance: Robenacoxib 20 mg

Excipients: Sodium metabisulfite (E223) (1 mg), Macrogol 400, Ethanol 96 per cent (128 mg), Poloxamer 188, Citric acid, Sodium hydroxide & Water for injections.

**CLINICAL INFORMATION / USES**

Target species: Cats and dogs.

For the treatment of pain and inflammation associated with orthopaedic or soft tissue surgery.

*(Please refer to Krka Robexera Cat Detailer for SPC summary information for cats)*

**CONTRAINDICATIONS**

Do not use in animals suffering from gastrointestinal ulceration.
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 Pregnancy, Lactation and Lay).
Do not use in breeding animals.

**ADMINISTRATION ROUTES AND DOSAGE**

Subcutaneous use (s.c.).

The recommended dose is 2 mg robenacoxib/kg body weight (1 mL of the veterinary medicinal product per 10 kg body weight). Administer the veterinary medicinal product approximately 30 minutes before the start of surgery, for example around the time of induction of general anaesthesia.

After soft tissue surgery in dogs, once daily treatment may be continued at the same dosage and at the same time every day for up to 2 days. The interchangeable use of the veterinary medicinal products containing robenacoxib in the form of tablets and solution for injection has been tested in target animal safety studies and was shown to be well tolerated by dogs.

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.

The stopper should be subjected to a maximum of 16 piercings.

**SPECIAL PRECAUTIONS FOR SAFE USE IN THE TARGET SPECIES**

The safety of the veterinary medicinal product has not been established in dogs less than 2 months of age, or in cats or dogs less than 2.5 kg body weight.

Use in animals with impaired cardiac, renal or hepatic function or those are dehydrated, hypovolaemic or hypotensive may involve additional risks. If use cannot be avoided, these animals require careful monitoring and fluid therapy. Use this veterinary medicinal product under strict veterinary monitoring in cases at risk of gastrointestinal ulceration, or if the animal previously displayed intolerance to other NSAIDs.

**SPECIAL PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE VETERINARY MEDICINAL PRODUCT TO ANIMALS**

For pregnant women, particularly near-term pregnant women, accidental injection and prolonged dermal exposure increases the risk for premature closure of the ductus arteriosus in the foetus.

Wash hands and exposed skin immediately after use of the veterinary medicinal product.

In case of accidental oral exposure (hand-to-mouth), prolonged dermal exposure or self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

**SPECIAL PRECAUTIONS FOR THE PROTECTION OF THE ENVIRONMENT**

Not applicable.

**ADVERSE EVENTS**

**Common** (1 to 10 animals / 100 animals treated): Injection site pain, Digestive tract disorder[1], Diarrhoea[1], Vomiting[1]

**Uncommon** (1 to 10 animals / 1 000 animals treated): Bloody diarrhoea, Blood in vomit

[1] Most cases were mild and recovered without treatment.

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.

**USE DURING PREGNANCY, LACTATION OR LAY**

Do not use in pregnant, lactating or breeding animals. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. The safety of the veterinary medicinal product has not been established in dog used for breeding.

**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 accordingly 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 veterinary medicinal 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 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 (dogs) 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 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.

**SYMPTOMS OF OVERDOSE (AND WHERE APPLICABLE, EMERGENCY PROCEDURES AND ANTIDOTES)**

In healthy young dogs aged 6 months, once daily subcutaneous administration of robenacoxib at doses of 2 (recommended therapeutic dose; RTD), 6 (3 times RTD), and 20 mg/kg (10 times RTD) for 9 administrations over a 5 week period (3 cycles of 3 consecutive once daily injections) did not produce any signs of toxicity, including gastrointestinal, kidney or liver toxicity and had no effect on bleeding time. Reversible inflammation at the injection site was noted in all groups (including controls) and was more severe in the 6 and 20 mg/kg dose groups.

The interchangeable use of veterinary medicinal products containing robenacoxib in the form of tablets and solution for injection 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 and 2.0 mg, 4.0 mg and 6.0 mg robenacoxib/kg subcutaneously) resulted in dose-related oedema, erythema, thickening of the skin and skin ulceration at the subcutaneous injection site and 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. No changes to blood pressure or the electrocardiogram were observed after single administration to healthy dogs of 2 mg/kg robenacoxib subcutaneously or 2 or 4 mg/kg intravenously. Vomiting occurred 6 or 8 hours post-dosing in 2 of 8 dogs administered the solution for injection at a dosage of 4 mg/kg intravenously.

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

**PHARMACEUTICAL PARTICULARS**

Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

**SHELF LIFE**

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after first opening the immediate packaging: 28 days.

**SPECIAL PRECAUTIONS FOR STORAGE**

Store in a refrigerator (2 °C – 8 °C). After first broaching the vial, store at temperature below 25 °C. Store in the original package in order to protect from light.

**NATURE AND COMPOSITION OF IMMEDIATE PACKAGING**

A cardboard box containing one amber type I glass vial of 20 ml, closed with a type I bromobutyl rubber stopper and an aluminium seal with plastic tear-off tab.

**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. 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.

**NAME OF THE MARKETING AUTHORISATION HOLDER**

KRKA, d.d., Novo mesto

**MARKETING AUTHORISATION NUMBER**

Vm 01656/5117 (GB)

**CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

POM-V: Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

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**REFERENCES**

**1.** Robexera SPC Robexera 40 mg chewable tablets for dogs - https://www.vmd.defra.gov.uk/productinformationdatabase/files/SPC_Documents/SPC_2610463.PDF

**2.** Robexera SPC Robexera 20 mg/ml solution for injection for cats and dogs - https://www.vmd.defra.gov.uk/ProductInformationDatabase/files/SPC_Documents/SPC_3090863.PDF

**3.** Regulatory approved Biowaiver demonstrating bioequivalence to the reference (Registration procedure UK(GB) Vm 01656/5117; PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT; available on https://www.vmd.defra.gov.uk/productinformationdatabase/files/UKPAR_Documents/UKPAR_3147525.PDF

**4.** Silber HE, et al.(2010) Population pharmacokinetic analysis of blood and joint synovial fluid concentrations of robenacoxib from healthy dogs and dogs with osteoarthritis. Pharm Res 27:2633-2645. doi: 10.1007/s11095-010-0262z .

**5.** Toutain, C.E., Brossard, P., King, S.B. et al. Six-month safety evaluation of robenacoxib tablets (Onsior™) in dogs after daily oral administrations. BMC Vet Res 14, 242 (2018).https://doi.org/10.1186/s12917-018-1566-1

**6.** Firocoxib: https://www.vmd.defra.gov.uk/ProductInformationDatabase/files/SPC_Documents/SPC_2280474.PDF

**7.** Cimicoxib: https://www.vmd.defra.gov.uk/ProductInformationDatabase/files/SPC_Documents/SPC_2740815.PDF

**8.** Lees, P., et al. (2022). Pharmacology, safety, efficacy and clinical uses of the COX-2 inhibitor robenacoxib. Journal of Veterinary Pharmacology and Therapeutics, 45, 325–351. https://doi.org/10.1111/jvp.13052.

**9.** Kongara K. , Chambers J.C. (2018) "Robenacoxib in the treatment of pain in cats and dogs: safety, efficacy and place in therapy." Veterinary medicine (Auckland, N.Z.) vol. 9 53-61. 15 Aug.2018, doi:10.2147/VMRR.S170893.

**10.** King JN, Jung M, Maurer MP, Schmid VB, Seewald W, Lees P. Effects of route of administration and feeding schedule on pharmacokinetics of robenacoxib in cats. Am J Vet Res. 2013 Mar;74(3):465-72. doi: 10.2460/ajvr.74.3.465.

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**13.** Metacam SPC 2.5 mg chewable tablets for dogs - https://www.vmd.defra.gov.uk/ProductInformationDatabase/files/SPC_Documents/SPC_2177183.PDF

**14.** Regulatory approved Biowaiver demonstrating bioequivalence to the reference (Registration procedure UK(GB) Vm 01656/5117; PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT; available on - https://www.vmd.defra.gov.uk/ProductInformationDatabase/files/UKPAR_Documents/UKPAR_2665658.PDF


Robexera contains Robenacoxib (POM-V).


Further information available in the SPC or from **KRKA UK Ltd**, Thames House, Waterside Drive, Langley, SL3 6EZ, United Kingdom | **Tel:** 020 7164 6156
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