Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Robexera 20 mg/ml Solution for Injection for Cats and Dogs

Date Created: December 2025

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Robexera 20 mg/ml Solution for Injection for Cats and Dogs
Applicant	KRKA, d.d., Novo mesto Smarjeska cesta 6 8501 Novo mesto Slovenia
Active substance	Robenacoxib
ATC Vetcode	QM01AH91
Target species	Cats and Dogs
Indication for use	For the treatment of pain and inflammation associated with orthopaedic or soft tissue surgery in cats and dogs.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Para 10) as amended.
Date of conclusion of the procedure	29/09/2025

I. SCIENTIFIC OVERVIEW

The product was submitted for a generic application for authorisation in Great Britain (GB), in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Para 10) as amended.

The reference product is Onsior 20 mg/ml Solution for Injection for Cats and Dogs authorised in GB (Vm: 52127/5021) and marketed by Elanco GmbH. The applicant claimed that the reference product is identical and provided a bioequivalence study.

Robexera 20 mg/ml Solution for Injection for Dogs and Cats contains 20 mg of Robenacoxib per ml. The product is indicated for cats and dogs for the treatment of pain and inflammation associated with orthopaedic or soft tissue surgery.

The recommended dose is 2 mg/kg of robenacoxib (equating to 1 ml per 10 kg of bodyweight) given subcutaneously, approximately 30 minutes prior to the start of surgery. After surgery, once daily treatment can be continued at the same dosage and at the same time every day for up to two days.

The distribution category in GB is POM-V, the same as the reference product.

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released on the market. It has been shown that the product can be safely used in the target species, any reactions observed are indicated in the SPC[1]. The product is safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy[2] of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

[1] SPC – Summary of Product Characteristics.
[2] Efficacy – The production of a desired or intended result.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains robenacoxib and the excipients sodium metabisulfite, macrogol 400, ethanol 96%, poloxamer 188, citric acid (anhydrous), sodium hydroxide and water for injections.

The container/closure system consists of one amber 20ml glass vial sealed with a bromobutyl rubber stopper and an aluminium seal, packaged in a cardboard box. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the absence of preservative are justified.

The product is an established pharmaceutical form, and its development is adequately described in accordance with the relevant regulatory guidelines.

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant regulatory guidelines.

II.C. Control of Starting Materials

The active substance is robenacoxib, an established active substance. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

II.C.4. Substances of Biological Origin

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form.

The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the production site have been provided demonstrating compliance with the specification. Control tests on the finished product are those appropriate for the pharmaceutical form.

II.F. Stability

Stability data on the active substance has been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

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

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

Due to the legal basis of the application, no new pharmacological or toxicological studies were submitted.

Warnings and precautions as listed on the product literature are comparable to those of the reference product and are adequate to ensure safety of the product to users/the environment.

III.A Safety Documentation

Pharmacological Studies

As is appropriate for the legal basis of the application, no new pharmacological studies were submitted.

The pharmacodynamics and pharmacokinetics of the active ingredients are the same as the reference product.

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 cats, using an *in vitro* whole blood assay, robenacoxib was approximately 500-fold selective for COX-2 (IC_{50} 0.058 µM) as compared to COX-1 (IC_{50} 28.9 µM). *In vivo*, robenacoxib solution for injection produced marked inhibition of COX-2 activity and had no effect on COX-1 activity. At the recommended dosage (2 mg/kg), analgesic, anti-inflammatory and anti-pyretic effects were demonstrated in an inflammation model, and in clinical trials, robenacoxib reduced pain and inflammation in cats undergoing orthopaedic or soft tissue surgery.

In dogs, robenacoxib was *in vitro* approximately 140-fold selective for COX-2 (IC_{50} 0.04 µM) as compared to COX-1 (IC_{50} 7.9 µM). *In vivo*, robenacoxib solution for injection produced marked inhibition of COX-2 activity and had no effect on COX-1 activity. At dosages ranging from 0.25 to 4 mg/kg, robenacoxib had analgesic, anti-inflammatory and anti-pyretic effects in an inflammation model with a rapid onset of action (1 h). In clinical trials at the recommended dose (2 mg/kg), robenacoxib reduced pain and inflammation in dogs undergoing orthopaedic or soft tissue surgery, and reduced the need for rescue treatment in dogs undergoing soft tissue surgery.

Toxicological Studies

As is appropriate for the legal basis of the application, no new toxicological studies were submitted.

User Safety

A user risk assessment was provided in compliance with the relevant guideline which shows that no risk for the user is expected if the product is used as directed.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore, the following applicant's user recommendations are appropriate:

- 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.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

Phase I:
The product will only be used in companion/non-food animals and as a result environmental exposure will be low. A Phase II ERA was not required.

IV. CLINICAL DOCUMENTATION

IV.II. Clinical Documentation

Due to the legal category of the application and as bioequivalence with the reference product was accepted, further efficacy studies were not required. The product is intended for administration in the same target species, via the same route of administration, and with the same posology as the reference product.

It is accepted that the generic product is of the same type of solution, contains the same concentration of the active substance and contains comparable excipients in similar amounts as the reference product.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics the benefit/risk profile of the product is favourable.

MODULE 4

POST- AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

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The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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