IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Robexera20 mg/ml solution for injection for cats and dogs

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PRODUCT SUMMARY

EU Procedure number	IE/V/0627/001/DC
Name, strength and pharmaceutical form	Robexera 20 mg/ml solution for injection
Active substance(s)	Robenacoxib
Applicant	Krka, d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto Slovenia
Legal basis of application	Generic application in accordance with Article 18 of Regulation (EU) 2019/6.
Date of completion of procedure	02/07/2025
Target species	Dogs and cats
Indication for use	For the treatment of pain and inflammation associated with orthopaedic or soft tissue surgery in dogs. For the treatment of pain and inflammation associated with orthopaedic or soft tissue surgery in cats.
ATC vet code	QM01AH91
Concerned Member States	BE, BG, CZ, DE, DK, EE, ES, FI, FR, HR, HU, IT, LV, LT, NL, NO, PL, PT, RO, SE, SI, SK, UK(NI)

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in the relevant articles of Regulation (EU) 2019/6. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland. The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

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. 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 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.

II. QUALITY ASPECTS

A. Qualitative and Quantitative Particulars

Each ml of product contains the active substance robenacoxib 20 mg, and the excipients sodium metabisulfite, macrogol 400, ethanol 96%, poloxamer 188, citric acid, sodium hydroxide, and water for injections. The container/closure system consists of a type I amber glass vial, closed with a type I bromobutyl rubber stopper and an aluminium seal with plastic tear-off tab. The choice of the formulation is justified. The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site. Process validation data for the manufacturing process has been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance robenacoxib is 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 has been provided. Compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

D. Control on Intermediate Products

Not applicable.

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 has been provided. Batch analytical data from the proposed production site has been provided demonstrating compliance with the specification.

F. Stability

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

G. Other Information

Not applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

This application for 'Robexera 20 mg/ml solution for injection for cats and dogs', containing the active substance robenacoxib, was submitted in accordance with the requirements of Article 18 of Regulation (EU) 2019/6 (that is, a generic application). The reference product cited is 'Onsior 20 mg/ml solution for injection for cats and dogs', (EU/2/08/089/020) which is authorised through the centralised procedure and is accepted as a suitable reference product.

The applicant has claimed a waiver from bioequivalence study requirements based on fulfilment of the criteria set out in section 7.1 b) of the Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/2000-Rev.4).
As bioequivalence with a suitable reference product has been accepted, results of safety tests are not required. The safety aspects of this product are identical to the reference product.

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

III. SAFETY ASSESSMENT

III.A Safety Testing

Pharmacological Studies

No proprietary pharmacological data were submitted. As this is a generic application according to Article 18 of Regulation (EU) 2019/6 and bioequivalence with a reference product has been accepted, results of pharmacodynamic or pharmacokinetic tests are not required**.** The pharmacological profile of the candidate product is not expected to differ from that of the reference product.

Toxicological Studies

No proprietary toxicological data were submitted. As this is a generic application according to Article 18 of Regulation (EU) 2019/6 and bioequivalence with a reference product has been accepted, results of toxicological tests are not required. The toxicological profile of the candidate product is not expected to differ from that of the reference product.

User Safety

The applicant has provided a user safety assessment conducted in accordance with the relevant guideline. It is accepted that the candidate product does not pose any greater risk to the user than the reference product. Similar user safety warnings as approved by the CVMP for the reference product were accepted for the candidate product and this is considered appropriate.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product, as follows:

'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 Risk Assessment

Phase I
The environmental risk assessment submitted was carried out in accordance with the relevant guidance. The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the VMP is intended only for use in non-food producing animals.
Conclusion
Based on the data provided, the ERA can stop at Phase I. The product is not expected to pose an unacceptable risk for the environment when used according to the SPC

IV. CLINICAL ASSESSMENT

As this is a generic application according to Article 18 of Regulation (EU) 2019/6 and bioequivalence with a reference product has been accepted, results of toxicological tests are not required**.** The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

As this is a generic application according to Article 18 of Regulation (EU) 2019/6, and bioequivalence with a reference product has been demonstrated, results of target animal safety tests are not required**.** No proprietary target animal tolerance data were therefore submitted, and it is accepted that when used in accordance with the proposed SPC, the product is not expected to pose any additional risk to the reference product in the target species.

The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies (pharmaceuticals and immunologicals)
No proprietary data were submitted. As this is a generic application (according to Article 18), and bioequivalence with a reference product has been accepted, results of efficacy tests are not required**.** The clinical efficacy profile of the candidate product is not expected to differ from that of the reference product formulation.

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 for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

VI. 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 HPRA website.
This section 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.
Changes:
None.