IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Rogiola 6 mg chewable tablets for cats

PRODUCT SUMMARY

EU Procedure number	IE/V/0785/005/DX/001
Name, strength and pharmaceutical form	Rogiola 6 mg chewable tablets for cats
Active substance(s)	Robenacoxib
Applicant	Krka, d.d., Novo mesto Smarješka cesta 6, 8501 Novo mesto, Slovenia.
Legal basis of application	Articles 18 and 62 of Regulation (EU) 2019/6
Date of completion of procedure	08/12/2025
Target species	Cats
Indication for use	For the treatment of pain and inflammation associated with acute or chronic musculoskeletal disorders. For the reduction of moderate pain and inflammation associated with orthopaedic surgery.
ATC vet code	QM01AH91
Concerned Member States	AT, BE, CY, DE, EL, ES, FR, IT, NL, PT, DK, FI, NO, SE.

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 and Concerned Member States.

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

The product contains 6 mg robenacoxib and the excipients cellulose microcrystalline, povidone, crospovidone, yeast powder, meat flavour, silica colloidal anyhdrous and magnesium stearate.
The container/closure system consists of OPA/Al/PVC/Aluminium perforated blister containing 6 or 10 tablets: 6 x 1, 10 x 1, 30 x 1 or 60 x 1 chewable tablet in perforated unit dose blisters, in a cardboard box.
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 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 has been provided.
There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

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 sites 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)

The products Rogiola 5, 10, 20 and 40 mg chewable tablets for dogs were granted marketing authorisations in accordance with Article 18 of Regulation (EU), 2019/6, as amended, following procedure IE/V/0785/001-004/DC.
This application for a grouped variation requiring assessment (VRA) was made in accordance with Article 62 of Regulation (EU) 2019/6 and concerns the addition of a new strength/potency, 6 mg (classification I.II.1.c), and a new target species, cats (classification G.I.10), to the existing marketing authorisations for Rogiola chewable tablets. The new strength is intended only for use in cats. In accordance with Article 18 of Regulation (EU) 2019/6, the applicant has cited a suitable reference product, 'Onsior 6 mg tablets for cats' (EU/2/08/089/001-003, 021 – Elanco GmbH) and has claimed bioequivalence of the candidate product with this reference product by means of an *in vivo* bioequivalence study. The candidate and reference formulations are intended for use in the same target species (cats), for the same indications and at the same dose rate.
As this is a generic product and bioequivalence with a reference product has been accepted, results of safety tests are not required. The safety aspects of this product are identical to those of the reference product.
The warnings and precautions listed on the product literature are the same as 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 pharmacodynamic data were submitted. As this is a generic product and bioequivalence with a reference product has been accepted, in accordance with Article 18, results of pharmacological tests are not required. Please refer to Part IV.A. for assessment of the *in vivo* bioequivalence study presented.

Toxicological Studies
No proprietary data were submitted. As this is a generic product, and bioequivalence with a reference product has been accepted, in accordance with Article 18 results of toxicological tests are not required.

User Safety
Noting that user safety for all authorised tablet strengths, up to and including a 40 mg tablet has already been assessed, and that the composition of the 6 mg strength and currently authorised tablet strengths are quantitatively proportional, it was accepted that provision of a new user risk assessment was not necessary. No additional hazard, exposure, or risk to users of the 6 mg tablet, as compared to the currently authorised tablet strengths is anticipated.

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, 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.
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.'

Environmental Risk Assessment
According to Figure 1 of the CVMP Reflection paper on the interpretation of Article 18(7) of Regulation (EU) 2019/6 (EMA/CVMP/ERA/622045/2020), the request of an ERA is not foreseen if the reference product of the generic was authorised after 1 October 2005.
Given that the reference product cited in this application was granted a marketing authorisation in the Union on 16/12/2008, in accordance with the aforementioned guidance the absence of an ERA for this grouped variation application concerning a generic product is accepted. The proposed SPC includes the standard statement "*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*." in Section 5.5 which is considered adequate.
In light of the above, it may be concluded that the candidate product will not present an unacceptable risk for the environment when handled, used, stored and disposed of in accordance with the recommendations included in the proposed SPC.

IV. CLINICAL ASSESSMENT

Given that the product concerned in this variation application is a generic product, and bioequivalence between the candidate and reference product formulations has been demonstrated, the results of efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

Pharmacology
A GLP-compliant *in vivo* bioequivalence study was provided in which bioequivalence between the 6 mg tablet strength of the candidate and reference formulations was demonstrated in cats. Following administration of one 6 mg candidate formulation tablet (equivalent to a dose of 1-2.4 mg/kg), maximum plasma concentrations of 2713.15 ng/ml (mean C_{max}) were reached at 0.5 hours (median T_{max}). The results of this study indicated that the 90 % confidence intervals for the test to reference mean ratio of C_{max} and AUC_t for robenacoxib fell within the pre-defined acceptance criteria.

Tolerance in the Target Species of Animals
No proprietary data were submitted. As the subject of this variation application is a generic product, and bioequivalence between the candidate and reference product formulations has been demonstrated, results of target animal safety tests are not required**.**
The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies
No proprietary data were submitted. Given that bioequivalence with a reference product has been accepted, in accordance with Article 18, results of efficacy tests are not required**.**

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.