Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A PROPOSED VETERINARY MEDICINAL PRODUCT

Robexera 5 mg Chewable Tablets for Dogs
Robexera 10 mg Chewable Tablets for Dogs
Robexera 20 mg Chewable Tablets for Dogs
Robexera 40 mg Chewable Tablets for Dogs

Date Created: November 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Robexera 5 mg Chewable Tablets for Dogs Robexera 10 mg Chewable Tablets for Dogs Robexera 20 mg Chewable Tablets for Dogs Robexera 40 mg Chewable Tablets for Dogs
Applicant	KRKA, d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto Slovenia
Active substance	Robenacoxib
ATC Vetcode	QM01AH91
Target species	Dogs
Indication for use	For the treatment of pain and inflammation associated with chronic osteoarthritis. For the treatment of pain and inflammation associated with soft tissue surgery.

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 13(1) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	07/08/2023

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical of these Onsior tablets for dogs product range

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains robenacoxib and the excipients Microcrystalline Cellulose, Povidone, Crospovidone, Yeast Powder, Meat Flavour, Colloidal Anhydrous Silica and Magnesium Stearate.

The container/closure system consists of OPA/AI/PVC/Aluminium perforated blister containing tablets. The particulars of the containers and controls performed are provided and conform to the regulation.

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

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European 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. The manufacturing process consists of manufacturing of granulate and compression mixture, tableting and packaging.

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

II.C. Control of Starting Materials

The active substance is robenacoxib, an established active substance described in the ASMF. 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 proposed production site have been provided demonstrating compliance with the specification. Control tests on the finished product are appropriate to adequately control the quality of the pharmaceutical form.

II.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 have 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

Shelf life of the veterinary medicinal product as packaged for sale: 2 years. Do not store above 30 °C. Store in the original package in order to protect from moisture.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

As this is a generic application in accordance with Article 13(1) of the Directive 2001/82/EC as amended, the bioequivalence with a reference product has been demonstrated, results of pharmaco-toxicological tests are not required.

Toxicological Studies

Not applicable due to the legal basis of the product.

User Safety

A user risk assessment was provided in compliance with the relevant guidelines.

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, 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.

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 non-food animals and as a result environmental exposure will be low. A Phase II ERA was not required.

IV. CLINICAL DOCUMENTATION

As this is a generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended, and bioequivalence with a reference product has been demonstrated, efficacy studies 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 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.

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

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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