Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Coxatab 25 mg Chewable Tablets for Dogs
Coxatab 57 mg Chewable Tablets for Dogs
Coxatab 100 mg Chewable Tablets for Dogs
Coxatab 225 mg Chewable Tablets for Dogs

Date Created: September 2024

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Coxatab 25 mg Chewable Tablets for Dogs Coxatab 57 mg Chewable Tablets for Dogs Coxatab 100 mg Chewable Tablets for Dogs Coxatab 225 mg Chewable Tablets for Dogs
Applicant	CP Pharma Handelsgesellschaft mbH, Ostlandring 13, 31303 Burgdorf, Germany
Active substance	Firocoxib
ATC Vetcode	QM01AH90
Target species	Dogs
Indication for use	For the relief of pain and inflammation associated with osteoarthritis in dogs. For the relief of post-operative pain and inflammation associated with soft-tissue, orthopaedic and dental surgery in 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 VMRs 2013 (Schedule 1, Para 10) as amended.
Date of conclusion of the procedure	28/06/2024

I. SCIENTIFIC OVERVIEW

This is a generic application for Coxatab 57 mg Chewable Tablets for Dogs and a generic hybrid application for the remaining tablet strengths due to a change in the pharmaceutical strength compared to the reference product. The reference product is Previcox 57 mg Chewable Tablet for Dogs which has been authorised in the UK since 2004.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains firocoxib and the excipients lactose monohydrate, microcrystalline cellulose, hydroxypropylcelulose, croscarmellose sodium, silica colloidal hydrated, magnesium stearate and chicken flavour.

The container/closure system consists of aluminium PVEC/PE/PVDC blisters within 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 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 product is manufactured in accordance with the relevant regulatory guidelines.

II.C. Control of Starting Materials

The active substance is firocoxib, an established active substance described in an 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

Scientific data and/or certificates of suitability issued by the EDQM have been provided and 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.

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 those appropriate for this pharmaceutical form.

II.F. Stability

Stability data on the active substance have 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: 4 years.
This veterinary medicinal product does not require any special storage conditions.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

As this is a generic application in accordance with Article 8 of VMRs 2013 (Schedule 1, Para 10) 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:,

- Wash hands after use of the product;
- In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician;
- Divided tablets should be returned to the original package.

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

IV.I. Pre-Clinical Studies

Pharmacology

Not required due to the legal basis of the application and bioequivalence with the reference product was established

Tolerance in the Target Species

Tolerance studies were not required because bioequivalence was established.

IV.II. Clinical Documentation

Not required due to the legal basis of the application.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the products are used in accordance with the Summary of Product Characteristics, the benefit/risk profile of the products are 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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