



**Veterinary
Medicines
Directorate**

**United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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Surrey KT15 3LS**

NATIONAL PROCEDURE

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY
MEDICINAL PRODUCT**

**OsteoCox 57mg Chewable Tablets for Dogs
OsteoCox 227mg Chewable Tablets for Dogs**

Date Created: April 2025

MODULE 1

PRODUCT SUMMARY

| | |
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| Name, strength and pharmaceutical form | OsteoCox 57mg Chewable Tablets for Dogs, Chewable tablet OsteoCox 227mg Chewable Tablets for Dogs, Chewable tablet |
| Applicant | Chanelle Pharmaceuticals Manufacturing Ltd, Loughrea, Co Galway, Loughrea, Ireland |
| Active substance | Firocoxib |
| ATC Vet code | 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

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|-------------------------------------|---|
| 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 | 28/03/2025 |

I. SCIENTIFIC OVERVIEW

These are generic applications in accordance with Article 8 of VMRs 2013 (Schedule 1, Para 10) as amended, for authorisations in Great Britain (GB) and Northern Ireland (NI). The reference products are Previcox Chewable Tablets for Dogs, which have been authorised in the UK since 13 September 2004. The applicant provided evidence of bioequivalence with the reference products.

OsteoCox tablets contain either 57mg or 227mg of firocoxib. The products are indicated for the relief of pain and inflammation associated with osteoarthritis in dogs, and for the relief of post-operative pain and inflammation associated with soft tissue, orthopaedic, and dental surgery in dogs. The dosage is 5mg per kg bodyweight once daily. The duration of treatment for osteoarthritis will be dependent on the response observed, and for post-operative pain it is advised to give for up to 3 days as needed, starting approximately 2 hours prior to surgery. Following orthopaedic surgery and depending on the response observed, treatment may be continued after the first 3 days, upon veterinary judgment.

The distribution category in GB and NI is POM-V, a veterinary medicinal product subject to prescription.

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 SPC¹. 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 efficacy² 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 firocoxib and the excipients lactose monohydrate, microcrystalline cellulose, hickory smoke flavour, hydroxypropyl cellulose, croscarmellose sodium, magnesium stearate, caramel (E150d), colloidal anhydrous silica, yellow iron oxide (E172) and red iron oxide (E172).

The container/closure system consists of cardboard boxes containing PVC/PVDC blisters with 20-micron aluminium foil. 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. The manufacturing method consists of a standard process, involving direct compression of a blend of the active substance and excipients.

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 firocoxib, an established active substance, supplied in accordance with an Active Substance Master File (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.

Those excipients which appear in the European Pharmacopoeia comply with the current version of their respective monographs. The specifications provided for the colouring agents are satisfactory and the flavouring is authorised for use in food in the EU, so is acceptable.

The blister packaging materials are described in detail and include confirmation of food contact approval.

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 those appropriate for this pharmacological 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

The shelf life of the veterinary medicinal product as packaged for sale is 3 years. Part used tablets should be returned to the blister and used within 28 days. The tablets should be stored in the original package in order to protect from light.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACOTOXICOLOGICAL)

Due to the legal basis of the applications, no new pharmacological or toxicological studies have been submitted. Appropriate evidence of bioequivalence to the reference products was provided.

Warnings and precautions as 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/the environment. In alignment with recently authorised products of the same pharmaceutical form, with the same concentrations of the active substance, a warning for pregnant women and those attempting to conceive, was included on product literature.

III.A Safety Documentation

Pharmacological Studies

The applicant submitted a study that supported bioequivalence between the 57mg strength of the test and reference products which was acceptable. The study was performed in dogs and bioequivalence was determined based on plasma concentrations following oral administration with OsteoCox and the reference product. *In vitro* comparative dissolution studies were supplied to support a biowaiver from the requirements to conduct *in vivo* bioequivalence studies for the 227mg strength tablet, in accordance with section 7.2 of the EMA Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/2000-Rev.4*). The dissolution studies conducted support equivalence between the 227mg and 57mg strength tablets.

Firocoxib is a non-steroidal anti-inflammatory drug (NSAID) belonging to the Coxib group, which acts by selective inhibition of cyclooxygenase-2 (COX-2) – mediated prostaglandin synthesis. COX-2 has been shown to be induced by pro-inflammatory stimuli and thought to be primarily responsible for the synthesis of prostanoid mediators of pain, inflammation, and fever. Coxibs, therefore, display analgesic, anti-inflammatory and antipyretic properties. In-vitro canine whole blood assays have shown that firocoxib exhibits approximately 380-fold selectivity for COX-2 over COX-1.

Following oral administration in dogs, at the recommended dose of 5mg per kg of bodyweight, firocoxib is rapidly absorbed and the time to maximal concentration (T_{max}) is 1.25 (± 0.85) hours. The peak concentration (C_{max}) is 0.52 (± 0.22) µg/ml (equivalent to approximately 1.5 µM), area under the curve (AUC 0-24) is 4.63 (±1.91) µg x hr/ml, and oral bioavailability is 36.9% (± 20.4). The elimination half-life (t_{1/2}) is 7.59 (± 1.53) hours. Firocoxib is approximately 96% bound to plasma proteins. Following multiple oral administrations, the steady state is reached by the third daily dose. Firocoxib is metabolised predominantly by the liver and elimination is principally in the bile and gastrointestinal tract.

User Safety

A user risk assessment was provided in compliance with the relevant guideline which shows that the products are not considered to present an unacceptable risk to the user when used as recommended.

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:

- This product can cause hypersensitivity (allergic) reactions. People with a known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the product.
- This product may be harmful following accidental ingestion.
- Care should be taken to avoid accidental ingestion.

- In order to prevent children from accessing the product, tablets should be administered and stored out of sight of children.
- Divided tablets should be returned to the open blister and inserted into the outer carton.
- Laboratory studies in rats and rabbits have shown evidence that firocoxib has the potential to effect reproduction and to induce malformation in foetuses. Pregnant women or those attempting to conceive should administer the product with caution.
- 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 product.

Environmental Safety

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

The applicant provided a Phase I environmental risk assessment containing sufficient information to conclude that the assessment ends at Phase I, and a Phase II ERA was not required. The product will only be used in non-food producing animals and as a result environmental exposure will be low. The products are not expected to pose a risk to the environment when used as recommended. Appropriate disposal advice has been provided in the SPC and QRD.

IV. CLINICAL DOCUMENTATION

As these are generic applications, and bioequivalence with the reference products has been established, efficacy studies are not required. The efficacy claims, dosing regimens, and pharmacology for this product are equivalent to those of the reference products.

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 products 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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