AGENCE NATIONALE DU
MEDICAMENT VETERINAIRE

Agence nationale du médicament vétérinaire (ANMV) – French agency for veterinary medicinal products
AGENCE NATIONALE DE SÉCURITÉ SANITAIRE de l'alimentation, de l'environnement et du travail – FRENCH AGENCY FOR FOOD, ENVIRONMENTAL AND OCCUPATIONAL HEALTH AND SAFETY
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

FICOXIL 57 MG CHEWABLE TABLETS FOR DOGS
FICOXIL 227 MG CHEWABLE TABLETS FOR DOGS

DATE: 07/05/201

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0400/001-002/DC
Name, strength and pharmaceutical form	Ficoxil 57 mg chewable tablets for dogs Ficoxil 227 mg chewable tablets for dogs
Applicant	LIVISTO Int'l, S.L. Av. Universitat Autònoma, 29 08290 Cerdanyola del Vallès (Barcelona) Spain
Active substance(s)	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 website http://www.anmv.anses.fr/

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	31 March 2021
Concerned Member States for original procedure	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, HU, IE, IS, IT, LT, LV, NL, NO, PL, PT, RO, SE, SI, SK, UK(NI)

I. SCIENTIFIC OVERVIEW

These applications were submitted in accordance with Article 13(1) of Directive 2001/82/EC, as amended by 2004/28/EC (generic veterinary medicinal product). The reference veterinary medicinal product is PREVICOX, which has been authorized via centralised procedure in 2004.
The products are produced and controlled using validated methods and tests, which ensure the consistency of the products released on the market.
It has been shown that the products can be safely used in the target species according to the recommendations described in the SPCs; however, as with other NSAIDs, serious adverse effects can occur and, in very rare cases, may be fatal. All the reactions observed are indicated in the SPCs.
The products are safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPCs.
The efficacy of the products was demonstrated according to the claims made in the SPCs.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The products contain firocoxib as active substance and the excipients povidone K30, lactose monohydrate, crospovidone, croscarmellose sodium, silica, colloidal anhydrous, magnesium stearate, beef flavor, red iron oxide and yellow

iron oxide. Two strengths are proposed: 57 mg and 227 mg. The packaging of the finished products is as described in their respective SPC. The particulars of the containers and controls performed are provided and conform to the regulation.
The products are an established pharmaceutical form and their development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The products are manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.
Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is firocoxib, 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 have been provided.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

E. Control on intermediate products

Not applicable.

F. Control Tests on the Finished Product

The finished products specifications control 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 products.
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.

G. Stability

Stability data for the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data for the finished products have been provided in accordance with applicable European guidelines, demonstrating the stability of the products throughout their shelf life when stored under the approved conditions.
An in-use shelf-life as detailed in the SPC has been supported by appropriate data.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

See paragraph IV.A.

Toxicological Studies

This application has been submitted in accordance with Article 13 (1) of Directive 2001/82/EC, as amended (generic product) thus, the results of toxicological tests are not required.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. It is accepted that the risks of the candidate products are comparable to those of the reference products.
Warnings and precautions as listed in the product literature are adequate to ensure safety to users of the products.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I: The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will only be used in non-food animals.

III.B Residues documentation

Not applicable.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacology

These applications are submitted in agreement with the Article 13(1) as generic applications. The cited reference products are PREVICOX 57 MG CHEWABLE TABLETS FOR DOGS and PREVICOX 227 MG CHEWABLE TABLETS FOR DOGS marketed by Boehringer Ingelheim Vetmedica.

Bioequivalence has been demonstrated based on an *in vivo* bioequivalence study and *in vitro* dissolution studies.
As this is a generic application according to Article 13(1), and bioequivalence with a reference product has been demonstrated, results of pharmacological tests are not required.

The pharmacological aspects of the products are identical to the reference products.

Tolerance in the Target Species of Animals

This application has been submitted in accordance with Article 13 (1) of Directive 2001/82/EC, as amended (generic product). Since bioequivalence between the products can be assumed, it is accepted that the tolerance of the candidate products is similar to the one of the reference products.

IV.B Clinical Studies

Applications for FICOXIL 57 MG CHEWABLE TABLETS FOR DOGS and FICOXIL 227 MG CHEWABLE TABLETS FOR DOGS were submitted according to Article 13 (1) of Directive 2001/82/EC (as amended by Directive 2004/28/EC) using PREVICOX 57 MG CHEWABLE TABLETS FOR DOGS and PREVICOX 227 MG CHEWABLE TABLETS FOR DOGS as reference products.

Considering that bioequivalence with the reference product has been demonstrated according to the Guideline on the Conduct of Bioequivalence Studies for Veterinary Medicinal Products (EMA/CVMP/EWP/016/2000-Rev.3), no clinical data were required, and reference can be made to the reference product PREVICOX for efficacy data.

Same indications as the ones mentioned for PREVICOX are claimed for FICOXIL, with the same recommended dosage regimen of 5 mg firocoxib/kg b.w. once daily.

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 risk benefit profile for the target species is favourable and the quality and safety of the products for humans and the environment is acceptable.