FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Firodyl 62.5 mg chewable tablets for dogs

Firodyl 250 mg chewable tablets for dogs

DATE: 2019.12.03.

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0385/001-002/DC
Name, strength and pharmaceutical form	Firodyl 62.5 mg chewable tablets for dogs Firodyl 250 mg chewable tablets for dogs
Applicant	CEVA SANTE ANIMALE 10 AVENUE DE LA BALLASTIERE 33500 LIBOURNE
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	Hybrid application in accordance with Article 13.3 of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	2019.10.23.
Date product first authorised in the Reference Member State (MRP only)	-
Concerned Member States for original procedure	AT, BE, BG, CZ, DE, DK, EE, EL, ES, FI, HU, IE, IT, LT, LV, LU, NL, NO, PL, PT, RO, SK, SE, UK

I. SCIENTIFIC OVERVIEW

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; the slight 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 62.5 mg or 250 mg of firocoxib and excipients hydroxypropylcellulose, croscarmellose sodium, microcrystalline cellulose, colloidal anhydrous silica, lactose monohydrate, magnesium stearate, yeast and chicken flavour.

The packagings of the finished products are as described on the SPCs. The particulars of the containers and controls performed are provided and conform to the regulation.
The products are established pharmaceutical forms 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.
The products are manufactured using conventional manufacturing techniques. Process validation for full-scale batches will be performed post-authorisation.

C. Control of Starting Materials

The active substance is firocoxib, a novel active substance not described in a Pharmacopoeia. 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

Scientific data 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.

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 on 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 on 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.

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 IV.A

Toxicological Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of pharmacological or toxicological tests are not required.

User Safety

The applicant provided a user safety assessment in accordance with the current guideline. It is accepted that the risks of the candidate products are comparable to those of the reference product.
Warnings and precautions as listed on 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.

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal products 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(3) as hybrid applications. The cited reference product is PREVICOX 57 MG CHEWABLE TABLETS FOR DOGS marketed by Merial.

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, and bioequivalence with a reference product has been demonstrated, results of pharmacological tests are not required.

The pharmacological aspects of this product are identical to the reference product.

Tolerance in the Target Species of Animals

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of tolerance study are not required.

IV.B Clinical Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claim for these products is based on the indications for use of the reference product.

The Applicant provided a field study conducted according to the palatability guideline EMA/CVMP/EWP/206024/2011, in order to support the palatability claim mentioned in section 4.9 of the SPC.

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.