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AGENCE NATIONALE DU
MEDICAMENT VETERINAIRE

FRENCH AGENCY FOR FOOD, ENVIRONNEMENTAL AND OCCUPATIONAL HEALTH SAFETY

FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

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PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

ROBENTROL TABLETS FOR DOGS

PRODUCT SUMMARY

EU procedure number	FR/V/0500/001-004/DC
Name, strength and pharmaceutical form	Robentrol tablets for dogs - 5 / 10 / 20 / 40 mg
Applicant	CHANELLE PHARMACEUTICALS MANUFACTURING IDA INDUSTRIAL ESTATE DUBLIN ROAD LOUGHREA H62 FH90 IRLANDE
Active substance(s)	Robenacoxib
ATC vetcode	QM01AH91
Target species	Dogs
Indication for use	For the treatment of pain and inflammation associated with chronic osteoarthritis in dogs. The recommended dose is 1 mg of robenacoxib per kg body weight with a range 1–2 mg of robenacoxib per kg body weight. Administer once daily at the same time every day. For the treatment of pain and inflammation associated with soft tissue surgery in dogs. The recommended dose of robenacoxib is 2 mg of robenacoxib per kg body weight with a range of 2-4 mg/kg body weight. Give as a single oral treatment prior to soft tissue surgery. The tablets should be administered without food at least 30 minutes prior to surgery. After surgery, once daily treatment may be continued for up to two further days.

Robentrol tablets for dogs	FR/V/0500/001-004/DC
CHANELLE PHARMACEUTICALS	DCP
Publicly available assessment report	

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Generic application in accordance with Regulation (EC) 2019/6 as amended.
Reference product (RP)	ONSIOR TABLETS FOR DOGS - 5 / 10 / 20 / 40 mg
Marketing authorisation holder	ELANCO
Marketing authorisation number EU procedure number	EU/2/08/089
Date of authorisation	16/12/2008

Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species.

The VMP is safe for the user, and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the VMP was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

A. Product description

The VMP contains the active substance robenacoxib at 5, 10, 20 or 40 mg/tablet and the following excipients: yeast flavour powder, microcrystalline cellulose PH101 and PH102, Beef Flavour, cellulose, povidone K30, crospovidone, silica colloidal anhydrous and magnesium stearate.

The packaging is adequate and described in the SPC.

The choice of the excipients are justified.

The VMP is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Description of the manufacturing method

The VMP is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

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

C. Production and control of starting materials

The active substance is robenacoxib, an established active substance not described in the European Pharmacopeia or a National pharmacopeia of a member state or a pharmacopeia of a third country. 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.

Scientific data have been provided.

D. Control tests carried out on isolated intermediates during the manufacturing process

Not applicable

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 VMP.

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.

F. Stability tests

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 product have been provided in accordance with applicable European guidelines, demonstrating the stability of the VMP throughout its shelf life when stored under the approved conditions.

3. SAFETY DOCUMENTATION (safety and residues tests)

A. Safety tests

Pharmacological studies

See part 4.

Toxicological studies

As this is a generic application according to Article 18 of Regulation (EC) 2019/6, results of safety tests are not required.

Other studies

As this is a generic application according to Article 18 of Regulation (EC) 2019/6, results of safety tests are not required.

User safety

The user safety assessment of this VMP is identical to the reference VMP.

Warnings and precautions as listed on the product literature are the same as those of the reference VMP and are adequate to ensure safety of the product to users.

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 VMP will only be used in non-food animals.

B. Residues documentation

Not applicable, as the product is intended for non-food producing species.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with the reference VMP has been demonstrated, efficacy studies are not required.

The efficacy claims for this VMP are equivalent to those of the reference VMP.

A. Pre-Clinical Studies

Pharmacology

Pharmaceutical form
The test and the reference products have the same pharmaceutical form (tablet).

Active substance qualitative and quantitative composition
The test and reference products have the same qualitative and quantitative composition in active substance: 5 - 10 – 20 & 40 mg of robenacoxib per tablet.

Bioequivalence studies
A bioequivalence study was realised in dogs with the candidate product ROBENTROL 40 MG TABLETS FOR DOGS and the reference product ONSIOR 40 MG TABLETS FOR DOGS, respectively.
The comparative dissolution between strengths of the test products was performed too.
Based on these data, the bioequivalence between the reference and the candidate products was satisfactory demonstrated.

Development of resistance and related risk in animals
Not relevant.

Dose determination and confirmation

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with the reference VMP is demonstrated, no dose determination and confirmation studies are required.

Tolerance in the target species of animals

As this is a generic application according to Article 18 of Regulation (EC) 2019/6, results of safety tests are not required.

The product literature accurately reflects the type and incidence of adverse effects, which might be expected.

B. Clinical trials

No clinical trials were performed.

As this is a generic application according to Article 18 of Regulation (EU) 2019/6 and bioequivalence with a reference VMP is demonstrated, clinical trials are not required.

The efficacy claims for this VMP are equivalent to those of the reference VMP.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP is 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 VMP for humans and the environment is acceptable.