FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT

FOR A VETERINARY MEDICINAL PRODUCT

LIBEO 10 MG CHEWABLE TABLETS FOR DOGS
LIBEO 10 mg (FR)
LIBEO VET (DK, NO)

LIBEO 40 MG CHEWABLE TABLETS FOR DOGS
LIBEO 40 mg (FR)
LIBEO VET (DK, NO)

Date: 28/10/2013

French agency for food, environnemental and occupational health safety– French Agency for Veterinary Medicinal Products
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MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0252/001/DC
Name, strength and pharmaceutical form	LIBEO 10 MG CHEWABLE TABLETS FOR DOGS LIBEO 40 MG CHEWABLE TABLETS FOR DOGS
Applicant	SOGEVAL 200 AVENUE DE MAYENNE ZONE INDUSTRIELLE DES TOUCHES 53000 LAVAL FRANCE
Active substance(s)	Furosemide
ATC Vetcode	QC03CA01
Target species	Dogs
Indication for use	Treatment of ascites and oedema, particularly associated with cardiac insufficiency

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	Generic applications in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	23/10/2013
Concerned Member States for original procedure	AT BE CZ DE DK EL ES FI HU IE IT LU NL NO PL PT RO SE UK

I. SCIENTIFIC OVERVIEW

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; the slight reactions observed are indicated in the SPC.
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 efficacy of the product was demonstrated according to the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The products LIBEO 10 MG chewable tablets for dogs and LIBEO 40 mg chewable tablets for dogs contain 10 mg furosemide per tablet and 40 mg furosemide per tablet respectively. Both products contain the following excipients: chicken flavor, yeast extract, microcrystalline cellulose, sodium croscarmellose, maltodextrin, silica, colloidal anhydrous, magnesium stearate and lactose monohydrate.

The tablets are packaged in blisters made of plastic film and aluminium foil. The particulars of the containers and controls performed are provided and conform to the regulation.

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

B. Method of Preparation of the Product

The product is 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 furosemide, an established substance described in the European 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 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.

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 product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.
An in-use shelf-life as detailed on 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

The applicant has conducted an *in vivo* and an *in vitro* bioequivalence studies according to the current guidelines. The results of these studies indicate that the tested products are

bioequivalent to the reference products FUROZENOL 10MG Tablet and FUROZENOL 40 MG Tablet marketed by VETOQUINOL.

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.

Toxicological Studies

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

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Ecotoxicity

The applicant has provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

III.B Residues documentation

These products are intended for non-food producing species, thus there was no necessity to provide data for this section.

IV. CLINICAL ASSESSMENT (EFICACY)

IV.A Pre-Clinical Studies (pharmaceuticals only)

Tolerance in the Target Species of Animals

The applicant has not provided a tolerance study which is acceptable because the tested product and the reference product are bioequivalent and the safety of the excipients of the tested formulation is acknowledged.

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 claims of the tested products are based on the reference product documentation.

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