College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Actikor 5 mg Film-coated Tablets for Dogs

Actikor 20 mg Film-coated Tablets for Dogs

NL/V/0151/001-002/DC

Created: October 2020

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0151/001-002/DC
Name, strength and pharmaceutical form	Actikor 5 mg Film-coated Tablets for Dogs Actikor 20 mg Film-coated Tablets for Dogs
Applicant	Ecuphar NV Legeweg 157-i 8020 Oostkamp Belgium
Active substance(s)	Benazepril Hydrochloride
ATC Vetcode	QC09AA07
Target species	Dog
Indication for use	Treatment of congestive heart failure associated with, in particular, dilated cardiomyopathy or mitral insufficiency.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu) or on the Medicines Evaluation Board – Veterinary Medicinal Products Unit website (https://www.diergeneesmiddeleninformatiebank.nl/nl).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	20 April 2011
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure	Belgium, Germany, Denmark, Finland (withdrawn), France, Ireland, Italy (withdrawn), Poland, Sweden and United Kingdom

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.

Actikor is authorized by means of a generic application. The reference products are Fortekor 5 and Fortekor 20, authorized under marketing authorization numbers REG NL 9772 and REG NL 8614, respectively. Both reference products are withdrawn in the Netherlands since 7 August 2018.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains benazepril hydrochloride (5 mg or 20 mg) and the excipients colloidal anhydrous silica, microcrystalline cellulose, Lactose monohydrate, pregelatinised maize starch, crospovidone, hypromellose, iron oxide yellow (E172), macrogol 8000, purified talc, titanium dioxide (E171) and zinc stearate.

Benazepril hydrochloride tablets 5mg & 20mg are packaged in aluminium foil blisters, consisting of forming foil and lidding foil. Pack sizes: 14, 28, 56, 84 and 140 tablets per blister.

The choice of the formulation is justified.

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 at a licensed manufacturing site.

The product is manufactured in accordance with the European Pharmacopoeia and relevant European guidelines.

C. Control of Starting Materials

The active substance is benazepril hydrochloride, an established active substance described in the European Veterinary 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.

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

D. Control on intermediate products

The tests performed during production are described and the results of routine tests, conforming to the specifications, are provided.

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.

F. 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.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

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

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.

III.A Safety Testing

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that dermal absorption over a longer period of time and ingestion of the product by a child are the main exposure routes.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

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 product will only be used in non-food animals.

IV. CLINICAL ASSESSMENT (EFFICACY)

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 for this product are equivalent to those of the reference product.

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 Heads of Veterinary Medicines Agencies website (www.HMA.eu).

This section 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.

Summary of change	**Section updated**	**Approval date**
Transfer of marketing authorisation from Accord Healthcare Ltd to Ecuphar N.V. (national variation)	Module 1, SPC	23 June 2011
Change in the (invented) name of the medicinal product Addition of a manufacturer responsible for batch release Change in Qualified Person (NL/V/0151/IB/001/G)	Module 1, SPC SPC N/A	12 July 2011
Extension of the shelf life of the finished product as packaged for sale (supported by real time data) (NL/V/0151/002/IB/002)	SPC	30 August 2011
Change from EDMF to CEP for the API manufacturer (NL/V/0151/001/IA/003)	N/A	9 July 2012
Change to in-process tests or limits applied during the manufacture of the finished product Minor change to an approved test procedure for the finished product NL/V/0151/IB/004/G	N/A	10 September 2012
Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions (NL/V/xxxx/IA/007/G)	N/A	16 August 2013
Renewal (NL/V/0151/001/R/001)	N/A	10 April 2016

Submission of an Updated Ph. Eur. Certificate for an active substance from an already approved manufacturer (NL/V/0151/002/IA/006)	N/A	2 June 2016
Change(s) in the safety database and/or major contractual arrangements for the fulfilment of pharmacovigilance obligations, and/or change of the site undergoing pharmacovigilance activities. (NL/V/xxxx/IA/021/G)	N/A	11 January 2017
Change in the QPPV and/or QPPV contact details and/or back-up procedure (NL/V/xxxx/IA/027/G)	N/A	11 October 2018