College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

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PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Benazepril Hydrochloride LeVet 5 mg tablets for dogs
Benazepril Hydrochloride LeVet 20 mg tablets for dogs

Created: February 2026

PRODUCT SUMMARY

EU procedure number	NL/V/0126/002-003/DC
Name, strength and pharmaceutical form	Benazepril Hydrochloride LeVet 5 mg tablets for dogs Benazepril Hydrochloride LeVet 20 mg tablets for dogs
Applicant	LeVet Pharma B.V. Willeskop 212 3421 GW Oudewater The Netherlands
Active substance(s)	Benazepril hydrochloride
ATC vetcode	QC09AA07
Target species	Dogs
Indication for use	Treatment of congestive heart failure

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*	Hybrid (5 mg) and generic (20 mg) application in accordance with Article 13 of Directive 2001/82/EC, as amended.
Reference product (RP)	Fortekor 20 mg coated tablets for dogs
Marketing authorisation holder	Novartis Consumer Health B.V.
Marketing authorisation number EU procedure number	*Nationally authorised reference product*
Date of authorisation	25 April 1995
Date of completion of the original decentralised procedure	30 January 2008
Concerned Member States for original procedure	AT, BE, CZ, EE, ES, FI, FR, IE, IT LU, NO, PL, PT, SK
Withdrawn CMS during original decentralised procedure	-

*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 reactions observed are indicated in the SPC.

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 5 mg or 20 mg benazepril hydrochloride and the excipients colloidal anhydrous silica (E551), microcrystalline cellulose (E460), anhydrous lactose, Colorcon Pigment Blend (iron oxides, E172), sodium cyclamate (E952), sodium starch glycolate, and magnesium stearate (E470b).

The container/closure system consists of PVC/PE/PVDC/Alu-foil blisters of 14 tablets each. 1, 2, 3, 4, 5, 6 or 7 blisters are packed in one carton.

The choice of the formulation is 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.

The VMP is manufactured using conventional manufacturing techniques. Process validation for full-scale batches will be performed post-authorisation.

C. Production and control of starting materials

The active substance is benazepril hydrochloride, an established 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.

Scientific data and/or certificates of suitability issued by the EDQM 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.

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.

The tests performed on the final VMP conform to the relevant requirements; any deviation from these requirements is justified.

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)

For the generic (20 mg) application according to Article 13 of Directive 2001/82/EC as amended by Directive 2004/28/EC, bioequivalence with a reference VMP has been demonstrated, and therefore results of pharmacological and toxicological tests are not required. For the hybrid application (5 mg), a waiver for *in vivo* bioequivalence is granted, based on: *in vitro* dissolution tests comparing the two strengths, the composition of both strengths is qualitatively identical, and their weight is proportionally identical; the weight of the 5 mg tablets is a quarter of that of the 20 mg tablets.

The pharmacological and toxicological aspects of this VMP are 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 and the environment.

A. Safety tests

Pharmacological studies

Not required.

Toxicological studies

Not required.

Other studies

Not required.

Observations in humans

Not required.

Development of resistance and related risk in humans

Not required.

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline, which shows that pregnant women should take special care to avoid accidental exposure, because ACE inhibitors have been found to affect the unborn child during pregnancy in humans.

The VMP should be stored out of reach of children. In case of accidental ingestion by children, medical advice should be sought immediately.

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

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 VMP will only be used in non-food animals.

B. Residues documentation

Not applicable.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

For the generic application (20 mg) according to Article 13 of Directive 2001/82/EC as amended by Directive 2004/28/EC, bioequivalence with a reference VMP has been demonstrated. For the 5 mg strength, a biowaiver was granted. Therefore, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

A. Pre-Clinical Studies

Pharmacology

The applicant has conducted a GLP study to show that Benazepril Hydrochloride LeVet is bioequivalent to Fortekor 20 mg tablets. Healthy beagle dogs were included in a two-period cross-over trial with 2 groups of 12 animals each (6 males + 6 females); a wash-out period of 8 days between treatments was used. Blood samples were taken for analyses of plasma concentrations for benazepril and benazeprilat, using a validated LC/MS method. Clinical observations (general health status evaluation, behaviour and appetite) of the animals were performed. The statistical analysis of the pharmacokinetic results of the trial data demonstrated that the test item and reference item are bioequivalent in dogs. The 90% confidence interval for AUC_t and C_{max} (parameters for the extent and rate of absorption respectively) for benazeprilat are included within the preset bioequivalence range of 80-125% for AUC and 70-143% for C_{max} for both compounds.

B. Clinical trials

No clinical trials were performed.

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.

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

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 VMP.

Sequence of significant variations

Changes to Part 2 of the dossier (quality)

Summary of change (Application number)	Approval date
Addition of new packaging (alu-alu blisters) with new shelf-life (NL/V/0126/002-003/IB/002)	22-08-2009
Addition of an active substance manufacturer with CEP (NL/V/xxxx/IA/002-003/G)	13-07-2011
Deletion of manufacturers, tightening specification limits in the finished product, extension shelf life finished product (NL/V/0126/IB/005/G)	18-12-2013
Change in manufacturer for batch release (NL/V/xxxx/IA/014/G)	29-06-2015
Change in active substance manufacturer incl CEP (NL/V/xxxx/IA/055/G)	26-04-2021
Addition of a manufacturer responsible for batch release, addition of secondary packaging site of the finished product (NL/V/0126/002-003/VNRA)	07-04-2023
Addition of a manufacturer (finished product) and change in manufacturing, in-process controls and specifications (NL/V/xxxx/A/069/G)	07-04-2023

Changes to Part 3 and/or Part 4 of the dossier (safety/efficacy)

Summary of change (Application number)	Supporting information	Approval date
N/A	N/A	N/A