

IPAR



**Publicly Available Assessment Report for a
Veterinary Medicinal Product**

BenazeVet 2.5 mg Tablets for cats and dogs

PRODUCT SUMMARY

EUProcedure number	IE/V/0660/001/MR
Name, strength and pharmaceutical form	BenazeVet 2.5 mg Tablets for cats and dogs
Active substances(s)	Benazepril hydrochloride
Applicant	Elanco GmbH Heinz-Lohmann-Strasse 4 27472 Cuxhaven Germany
Legal basis of application	Informed consent application (Article 13c of Directive No 2001/82/EC)
Date of Authorisation	20 November 2020
Target species	Cats, Dogs
Indication for use	Dogs: Treatment of congestive heart failure. Cats: Reduction of proteinuria associated with chronic kidney disease.
ATCvet code	QC09AA07
Concerned Member States	UK

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Fortekor 2.5 mg tablets for cats and dogs (VPA 22020/017/001). The initial application for Fortekor 2.5 mg tablets for cats and dogs was assessed before there was a requirement to have a public assessment report; therefore no details in this section are available.

II. QUALITY ASPECTS**A. Composition**

The products contain 2.5 mg benazepril hydrochloride and excipients cellulose microcrystalline, crospovidone, povidone, basic butylated methacrylate copolymer, hydrogenated castor oil, silicon dioxide anhydrous, sodium laurilsulphate, dibutyl sebacate, silica colloidal anhydrous, yeast powder and vanillin.

The container system consists of aluminium/aluminium blister packs with 14 tablets/blister. Cardboard box with 2 blisters (28 tablets).

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. 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 benazepril hydrochloride, an established active substance described in the European Pharmacopoeia (Ph. Eur). 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.

Ph. Eur. compliant or in-house specifications are provided for all excipients.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

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

E. Control Tests on Intermediate Products

The results of tests performed for release on batches of the intermediate products are provided and comply with the specifications. The specification was considered suitable for the analysis of the intermediate product.

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. StabilityStability of the Active Substance

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 of the Finished Product

Data were supplied for batches tested under VICH conditions. The products met all requirements of the proposed shelf-life, as specified in the SPC.

H. Genetically Modified Organisms

Not Applicable.

J. Other Information

Not Applicable.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

See section I

IV. CLINICAL ASSESSMENT

See section I

V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the original data submitted, the HPRA considered that the product demonstrated adequate evidence of efficacy for the approved indications as well as a satisfactory benefit/risk profile and therefore granted a marketing authorisation.

VI. 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 HPRA website. 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.

Changes

None.