IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Benazecare Flavour 20 mg Tablets for Dogs

PRODUCT SUMMARY

EU Procedure Number	IE/V/452/002 (formerly UK/V/0264/002)
Name, Strength, Pharmaceutical Form	Benazecare Flavour 20 mg Tablets for Dogs
Active Substances(s)	Benazepril hydrochloride
Applicant	Ecuphar NV, Legeweg 157-I, 8020 Oostkamp, Belgium
Legal Basis of Application	Generic application (Article 13(1) of Directive No 2001/82/EC)
Target Species	Dogs
Indication For Use	Treatment of congestive heart failure in dogs
ATC Code	QC09AA07
Date of completion of the original mutual recognition procedure	21 November 2007 (UK)
Date product first authorised in the Reference Member State (MRP only)	24 August 2006 (UK & IE)
Concerned Member States for original procedure	Austria Belgium France Germany Ireland (now RMS) Luxembourg Netherlands Spain UK added via RMS change

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the 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 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 product contains the active substance benazepril hydrochloride and excipients lactose monohydrate, pregelatinized starch, croscarmellose sodium, castor oil hydrogenated and beef flavour 201627.

The tablets are supplied in blister packs made of an aluminium/PVC laminate used to form tablet containing blisters with an aluminium lidding foil, coated with heat sealable lacquer. Tests of identity, appearance and dimensions are performed. The particulars of the containers and controls performed are provided and conform to the regulation.

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 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 benazepril hydrochloride, an established active substance. Although there is no pharmacopoeial monograph for benazepril hydrochloride, the manufacturer's specification covers appropriate aspects. 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.

H. Genetically Modified Organisms

Not applicable

J. Other Information

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 48 hours.
Any divided tablet portion remaining after 48 hours should be discarded.

Special precautions for storage

Do not store above 25°C.
Store in a dry place.

Divided tablets should be stored in the blister pack**.**
The blister pack should be inserted back into the cardboard box.

III SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

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 is/are identical to the reference product.
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 / consumers.

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 is/are identical to the reference product.
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 / consumers.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline which shows that skin contact is the most likely route of exposure to the product Accidental oral exposure is also identified as a possible route of exposure. The agreed user warnings include information on how to avoid exposure.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

IV. CLINICAL ASSESSMENT

IV.A Pre-Clinical Studies

Pharmacology

The application for a marketing authorisation was based on the essential similarity of this product to the established product Fortekor 20. The company showed that the products were essentially similar by demonstrating bioequivalence between this product and Fortekor 5. The company have fully justified the use of the lower tablets strength, i.e. tablets contain 5 mg of active substance, in these studies. The bioequivalence study commissioned by the Applicant compared the two products in terms of how much of each active ingredient, benazepril hydrochloride, was absorbed into the blood stream when the products were given as recommended, i.e. by mouth. It demonstrated that this product complied with the official definition of essential similarity. This means that no further information was required to demonstrate the efficacy of the product or its safety for dogs

Tolerance in the Target Species of Animals

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.

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

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.