Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

MiPet Benazapet 2.5 mg Tablets for cats and dogs

Date Created: November 2015

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	MiPet Benazapet 2.5 mg Tablets for cats and dogs
Applicant	Elanco Europe Ltd. Lilly House Priestley Road Basingstoke Hampshire RG 24 9NL
Active substance	Benazapril hydrochloride
ATC Vetcode	QC09AA07
Target species	Cats and dogs
Indication for use	Dogs: Treatment of congestive heart failure. Cats: Reduction of proteinuria associated with chronic kidney disease.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Informed Consent application in accordance with Article 13c of Directive 2001/82/EC as amended.

I. SCIENTIFIC OVERVIEW

The quality/safety/efficacy aspects of this product are identical to Fortekor 2.5 mg Tablets for Cats and Dogs. 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. 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 benefit/risk profile of the product(s) is favourable

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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 Product Information Database of the Veterinary Medicines Directorate website.

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The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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