Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

EviVet IncoVet Syrup, 40 mg/ml, Dogs

Date Created:
March 2022

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	EviVet IncoVet Syrup, 40 mg/ml, Dogs
Applicant	Vetoquinol UK Ltd Vetoquinol House Great Slade, Buckingham Industrial Park Buckingham Buckinghamshire MK18 1PA
Active substance	Phenylpropanolamine 40.28 mg (Equivalent to 50 mg phenylpropanolamine hydrochloride)
ATC Vetcode	QG04BX91
Target species	Dogs
Indication for use	Treatment of urinary incontinence associated with urethral sphincter incompetence in the bitch. Efficacy has only been demonstrated in ovariohysterectomised bitches.

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 13 (c) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	25/02/2022

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product is/are identical to Propalin Syrup 40 mg/ml Dogs. The initial application for Propalin Syrup 40 mg/ml 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 is favourable.

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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