Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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National Procedure

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Flyclanil 5% Pour-on Suspension for Sheep

Date created: December 2021

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Flyclanil 5% Pour-on Suspension
Applicant	Elanco Europe Ltd Form 2, Bartley Way Bartley Wood Business Park Hook RG27 9XA United Kingdom
Active substance	Dicyclanil (ISO)
ATC Vetcode	QP53AX24
Target species	Sheep
Indication for use	Prevention of blowfly strike due to *Lucilia sericata* on sheep. Prevention of blowfly strike due to *Wohlfahrtia magnifica* on sheep

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.

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of these products are identical to those of CliK 5% Pour-on Solution. The initial application for Clik 5% Pour-on Solution 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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