Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Deltamole 7.5 mg/ ml Pour-On Suspension for Cattle

Date Created: 16th February 2015

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Deltamole 7.5 mg/ ml Pour-On Suspension for Cattle
Applicant	Intervet UK Ltd Walton Manor Walton Milton Keynes Buckinghamshire MK7 7AJ
Active substance	Deltamethrin
ATC Vetcode	QP53AC11
Target species	Cattle
Indication for use	Control of biting and nuisance flies of cattle, including *Haematobia irritans*, *Hippobosca equina*, *Stomoxys calcitrans*, *Musca autumnalis* and *Musca domestica*. Control of biting and sucking lice of cattle, including *Damalinia bovis*, *Haematpoinus eurysternus*, and *Linognathus vituli*.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Veterinary Medicines Directorate website (www.vmd.defra.gov.uk)

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 and efficacy aspects of this product is/are identical to Butox Swish, Pour-On Suspension 0.75% w/v. The initial application for Butox Swish, Pour-On Suspension 0.75% w/v was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

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 benefit/risk profile of the product(s) 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.

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

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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