

ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

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

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Armitage Pet Care Insecticidal Flea Shampoo and Conditioner

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Armitage Pet Care Insecticidal Flea Shampoo and Conditioner
Applicant	Sinclair Animal and Household Care Ltd
Active substance(s)	Piperonyl Butoxide Pyrethrum Extract 25% (equivalent to Pyrethrins)
ATC Vetcode	QP53AC51
Target species	Dogs
Indication for use	For the control of fleas on dogs and puppies over 12 weeks of age.

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

PUBLIC ASSESSMENT REPORT

application in accordance of Directive 2001/82/EC as

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspect of this product is/are identical to Bearphar Dog Flea Shampoo. The initial application for Bearphar Dog Flea Shampoo 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 for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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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