



**ASSURING THE SAFETY, QUALITY AND EFFICACY  
OF VETERINARY MEDICINES**

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

**NATIONAL PROCEDURE**

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY  
MEDICINAL PRODUCT**

**Bob Martin Flea Tablets 57 mg for Large Dogs**

## MODULE 1

### PRODUCT SUMMARY

Name, strength and pharmaceutical form	Bob Martin Flea Tablets 57 mg for Large Dogs
Applicant	Elanco Europe Ltd Lilly House Priestly Road Basingstoke Hampshire RG24 9NL
Active substance(s)	Nitenpyram
ATC Vetcode	QP53BX02
Target species	Dogs
Indication for use	Treatment of flea infestation ( <i>C. felis</i> ) on dogs

## **MODULE 2**

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

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## **MODULE 3**

### **PUBLIC ASSESSMENT REPORT**

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

The quality / safety / efficacy aspects of this product is/are identical to Capstar 57 mg Tablets for Large Dogs. The initial application for Capstar 57 mg Tablets for Large 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 for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

## **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](http://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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