



**Veterinary
Medicines
Directorate**

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

NATIONAL PROCEDURE

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

Beaphar Flea 57 mg Tablets for Medium & Large Dogs

Date Created: February 2025

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Beaphar Flea 57 mg Tablets for Medium & Large Dogs
Applicant	Elanco Europe Ltd Form 2, Bartley Way Bartley Wood Business Park Hook RG27 9XA United Kingdom
Active substance	Nitenpyram
ATC Vetcode	QP53BX02
Target species	Dogs
Indication for use	Treatment of flea infestations (<i>C. felis</i>)

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 accordance with Article 8 of VMRs 2013 (Schedule 1, Para 9) as amended.
Date of conclusion of the procedure	17/02/2025

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product 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.

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 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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