



Veterinary  
Medicines  
Directorate

United Kingdom  
Veterinary Medicines Directorate  
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**DECENTRALISED PROCEDURE**

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

**Felidale 1.25 mg Coated Tablets for Cats**

**Date Created: 21<sup>st</sup> February 2018**

**PuAR correct as of 27/07/2018 when RMS was transferred to DE. Please contact the  
RMS for future updates.**

## **MODULE 1**

### **PRODUCT SUMMARY**

|  |   |
|--|---|
| EU Procedure number                    | UK/V/0655/001/DC  |
| Name, strength and pharmaceutical form | Felidale 1.25 mg Coated Tablets for Cats  |
| Applicant                              | Dechra Limited<br>Snaygill Industrial Estate<br>Keighley Road<br>Skipton<br>North Yorkshire<br>BD23 2RW                                     |
| Active substance(s)                    | Thiamazole  |
| ATC Vetcode                            | QH03BB02  |
| Target species                         | Cats  |
| Indication for use                     | For the stabilisation of hyperthyroidism in cats prior to surgical thyroidectomy.<br>For the long-term treatment of feline hyperthyroidism. |

## **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](http://www.gov.uk/check-animal-medicine-licensed)

As the product was refused a marketing authorisation, a Summary of Product Characteristics was not approved for this product.

## **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. |
| Date of conclusion of the <mutual recognition> <decentralised>procedure<br><i>For Repeat Use or Extension, add date of completion of current procedure</i> | 15 <sup>th</sup> November 2017  |
| Concerned Member States for original procedure   | Germany   |

#### **I. SCIENTIFIC OVERVIEW**

The quality, safety and efficacy aspects of this product are identical to Felimazole 1.25 mg Coated Tablets for Cats.

#### **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 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](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.

[www.gov.uk/check-animal-medicine-licensed](http://www.gov.uk/check-animal-medicine-licensed)