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: 21st 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 Snaygill Industrial Estate Keighley Road Skipton North Yorkshire 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. 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)

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 *For Repeat Use or Extension, add date of completion of current procedure*	15th 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.

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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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