Veterinary Medicines Directorate

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

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Felidale 2.5 mg Coated Tablets for Cats

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/0415/001/DC
Name, strength and pharmaceutical form	Felidale 2.5 mg Coated Tablets for Cats
Applicant	Dechra Limited Dechra House Jamage Industrial Estate Talke Pits Stoke-on-Trent Staffordshire ST7 1XW UK
Active substance	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 Heads of Medicines Agencies (veterinary) (HMA(v)) website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Copycat application in accordance with Article 13c of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	22nd February 2012
Date product first authorised in the Reference Member State (MRP only)	Not applicable.
Concerned Member States for original procedure	France, Germany, Ireland, The Netherlands

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product is/are identical to the original product. The initial application for Felimazole 2.5 mg Coated Tablets for Cats 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 Heads of Medicines Agencies (veterinary) (HMA(v)) website (www.hma.eu).

This section 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.

None.