AGENCE NATIONALE DU
MEDICAMENT VETERINAIRE

FRENCH AGENCY FOR FOOD, ENVIRONNEMENTAL AND OCCUPATIONAL HEALTH SAFETY

FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

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PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Purmazole 5 mg/mL Oral Solution for Cats

06 July 2026

PRODUCT SUMMARY

EU procedure number	FR/V/0517/001/DC
Name, strength and pharmaceutical form	Purmazole 5 mg/mL Oral Solution for Cats Felipex 5 mg/ml Oral Solution for Cats (IE, SE)
Applicant	Chanelle Pharmaceuticals Manufacturing Limited Ida Industrial Estate Dublin Road H62 FH90 Co Galway Ireland
Active substance(s)	Thiamazole
ATC vetcode	QH03BB02
Target species	Cats
Indication for use	For the stabilisation of hyperthyroidism prior to surgical thyroidectomy. For the long-term treatment of feline hyperthyroidism.

Purmazole 5 mg/mL Oral Solution for Cats	FR/V/0517/001/DC
Chanelle Pharmaceuticals Manufacturing Limited	DCP
Publicly available assessment report	

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Hybrid application in accordance with Article 19(1) of Regulation (EC) 2019/6 as amended.
Reference product (RP)	FELIMAZOLE 5 MG COMPRIMES ENROBES POUR CHATS (Felimazole 5 mg coated tablets for cats)
Marketing authorisation holder	Dechra Regulatory B.V.
Marketing authorisation number EU procedure number	FR/V/6936990 0/2004 IE/V/0505/001 (previously UK/V/0198/001)
Date of authorisation	21 July 2004 (first authorized in the UK: 22/01/2002)
Date of completion of the original decentralised procedure	05 March 2026
Concerned Member States for original procedure	FR, DE, ES, IT, RO
Concerned Member States for subsequent recognition procedure (FR/V/0517/001/E/001)	AT, BE, CZ, DK, FI, HU, IE, IS, LI, LU, NL, NO, PL, PT, SE, UK(NI)

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

The VMP is safe for the user, and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the VMP was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

2. QUALITY DOCUMENTATION

A. Product description

The VMP contains 5 mg/mL thiamazole as active substance and the excipients sodium benzoate, hypromellose, povidone K30, glycerol, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate, citric acid, simethicone emulsion, honey flavour and purified water.

The container closure system is a polyethylene terephthalate (PET) amber bottle closed with a child-resistant cap with an incorporated cap insert.

Details of the graduated syringe with which the VMP will be administered are provided.

The choice of the formulation and the presence of a preservative are justified.

The VMP is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Description of the manufacturing method

The VMP is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation data on the VMP have been presented in accordance with the relevant European guidelines.

The VMP is manufactured in accordance with the European Pharmacopoeia (Ph. Eur.) and relevant European guidelines.

C. Production and control of starting materials

The active substance is thiamazole, an established active substance described in the European Pharmacopeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

Scientific data and/or certificates of suitability issued by the EDQM have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

D. Control tests carried out on isolated intermediates during the manufacturing process

Not applicable.

E. Control tests on the finished product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification and their limits have been justified and are considered appropriate to adequately control the quality of the VMP.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

F. Stability tests

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the VMP throughout its shelf life when stored under the approved conditions.

The in-use shelf life of the broached VMP is supported by the data provided. The recommendations in the product leaflet should be followed.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION

A. Safety tests

Pharmacological studies

See part 4.

Toxicological studies

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of toxicological tests are not required.

User safety

A qualitative user risk assessment (URA) has been included to take into account the differences in composition/formulation with the reference product.

Precautions as listed in the product literature are adequate to ensure safety to users of the VMP.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the VMP will only be used in non-food animals.

4. EFFICACY DOCUMENTATION

A. Pre-Clinical Studies

Pharmacology

This application has been submitted in accordance with Article 19(1) of Regulation (EU) 2019/6 (hybrid veterinary medicinal product), on the basis that there is a change in the pharmaceutical form compared to the reference product. It is accepted that the applicant has cited a suitable reference product, and that the candidate product is intended to be used for the same indications, in the same target species, via the same route of administration and at the same posology as the reference product.

The applicant has conducted a two-period, two-sequence crossover bioequivalence study in adult healthy cats, carried out largely in accordance with the Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/2000-Rev.4) and the VICH GL52 guideline Bioequivalence: Blood Level Bioequivalence Study (EMA/CVMP/VICH/751935/2013-Corr).

The results of this study indicate that the 90% confidence intervals for both AUCt and Cmax lie within the narrower limits of 80-125%. Based on these data, it could be accepted that the test product, Purmazole oral solution, is bioequivalent to the reference product, Felimazole coated tablets for cats.

Dose determination and confirmation

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of dose determination and confirmation studies are not required.

The same administration route and dosage as the reference product has been retained in the product literature.

Tolerance in the target species of animals

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, results of tolerance tests are not required.

The product literature accurately reflects the type and incidence of adverse effects, which might be expected.

B. Clinical trials

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference VMP.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the VMP for humans and the environment is acceptable.