AGENCE NATIONALE DU

MEDICAMENT VETERINAIRE

FRENCH AGENCY FOR FOOD, ENVIRONNEMENTAL AND OCCUPATIONAL HEALTH SAFETY

FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

OPHTALON VET, 10 mg/g, eye ointment for dogs and cats

PRODUCT SUMMARY

EU procedure number	FR/V/0523/001/DC
Name, strength and pharmaceutical form	Ophtalon Vet 10 mg eye ointment for dogs and cats
Applicant	DOMES PHARMA 3 RUE ANDRE CITROEN 63430 PONT DU CHATEAU
Active substance(s)	Chloramphenicol
ATC vetcode	QS01AA01
Target species	Dogs and cats
Indication for use	Treatment of ocular bacterial infections

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 of Regulation (EC) 2019/6 as amended.
Reference product (RP)	OPHTALON 10 MG/G POMMADE OPHTALMIQUE POUR CHIENS ET CHATS
Marketing authorisation holder	DOMES PHARMA
MS where the RP is or has been authorised	FR
Marketing authorisation number EU procedure number	National procedure FR/V/3787889 6/1989
Date of authorization	04/04/1989
Date of completion of the decentralised procedure	10/06/2026
Concerned Member States for procedure	AT, BE, DE, DK, EL, ES, FI, FR, IE, IT, LU, NL, NO, PL, PT, RO, SE

*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 (physicochemical, biological or microbiological information)

A. Product description

The VMP contains 10 mg of chloramphenicol as active substance and the excipients: vitamin A (all-(E)-retinol palmitate), white soft paraffin and liquid paraffin.

The container/closure system is an aluminium tube with a polyethylene nozzle and a polypropylene cap.

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

The selection of the manufacturing process of the active substance and the finished product is explained.

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.

C. Production and control of starting materials

The active substance is chloramphenicol, 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.

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this VMP.

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 VMP is supported by the data provided. The recommendations in the product leaflet should be followed.

3. SAFETY DOCUMENTATION (safety and residues tests)

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

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 essential similarity to the reference VMP has been demonstrated, results of toxicological tests are not required.

User safety

The applicant has submitted a user risk assessment (URA) in accordance with the current CVMP guidance, 'Guideline on user safety for Veterinary Medicinal Products' (EMEA/CVMP/543/03-Rev.1).

Warnings and precautions as listed on 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.

B. Residues documentation

Not applicable. Dogs and cats are non-food producing animals.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and essential similarity to the reference VMP has been demonstrated, efficacy studies are not required.

The efficacy claims for this VMP are equivalent to those of the reference VMP.

A. Pre-Clinical Studies

No pre-clinical studies were performed.

Development of resistance and related risk in animals

The applicant has provided a summary of the epidemiological situation based on bibliographical information and surveillance data in relation to resistance to amphenicols in relevant target bacteria per target animal species. Adequate warnings and precautions appear on the product literature.

Dose determination and confirmation

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

Tolerance in the target species of animals

No target animal tolerance data specific to the candidate product have been presented. As this is an application submitted in accordance with article 19(1) of Regulation (EU) 2019/6, a so called hybrid application, and considering that essential similarity to the reference product has been established, it is accepted that the tolerance of the candidate product will be similar to those of the reference product.

B. Clinical trials

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

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).