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FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

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PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Fluo-clear eye drops solution for dogs and cats

PRODUCT SUMMARY

EU procedure number	FR/0516/001/DC
Name, strength and pharmaceutical form	Fluo-clear 4.4 g/ml eye drops solution for dogs and cats
Applicant	DOMES PHARMA 3 RUE ANDRE CITROEN 63430 PONT DU CHÂTEAU FRANCE
Active substance(s)	Fluorescein
ATC vetcode	QS01JA01
Target species	Dogs and Cats
Indication for use	Instill 1 to 2 drops of eye drops into the eye.

Fluo-clear eye drops solution for dogs and cats	FR/0516/001/DC
DOMES PHARMA	
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).

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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)	Fluorescéine collyre en solution pour chiens et chats
Marketing authorisation holder	DOMES PHARMA
Marketing authorisation number EU procedure number	FR/V/0061630 6/1988
Date of authorisation	21/04/1988

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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 2 mg of fluorescein sodium (equivalent to 1.76 mg of fluorescein) and the excipients sodium chloride and water for injections.

The container/closure system is a low density polyethylene single-dose container of 0.4 mL packaged in polyethylene / aluminium / polyethylene based layer / PET film pouch.

The absence of preservative is 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.

C. Production and control of starting materials

The active substance is fluorescein sodium, 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.

Certificate of suitability issued by the EDQM has 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

A re-test period is set in the Certificate of Suitability of the active substance.

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.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

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

The toxicological aspects of this VMP are identical to the reference VMP.

Warnings and precautions as listed on the product literature are the same as those of the reference VMP and are adequate to ensure safety of the product to users and to the environment.

User safety

The applicant has provided a user safety assessment in compliance with the relevant guidelines

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

Environmental Risk Assessment

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.

If used as recommended the product will a have a negligible environmental impact.

B. Residues documentation

Not applicable, as the candidate product is intended for non-food producing species.

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 with 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

Pharmacology

Pharmaceutical form
The test and the reference products have the same pharmaceutical form: eye drops solution

Active substance qualitative and quantitative composition
The test and reference products have the same qualitative and quantitative composition in active substance: 1.76 mg of fluorescein (as sodium salt) per each single-dose container of 0.4 mL

Bioequivalence studies
As the product acts only locally, the bioequivalence cannot be demonstrated by bioavailability studies.
The essential similarity was demonstrated between the two products according to pharmaceutical equivalence.

Development of resistance and related risk in animals

Not applicable.

Dose determination and confirmation

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

Tolerance in the target species of animals

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

The tolerance profile of the product is similar to that of the reference product.

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 essential similarity with the reference VMP has been demonstrated, clinical trials 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.