



**FRENCH AGENCY FOR FOOD, ENVIRONMENTAL AND OCCUPATIONAL
HEALTH SAFETY**

FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS

**14 RUE CLAUDE BOURGELAT – PARC D’ACTIVITES DE LA GRANDE MARCHÉ
JAVENE – CS 70611 – 35306 FOUGERES**

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY
MEDICINAL PRODUCT**

**RILEXINE 150 MG/ML, powder and solvent for solution for
injection for dogs and cats**

RILEXINE 150 MG/ML, powder and solvent for solution for injection for dogs and cats	FR/V/0519/001/DC
VIRBAC	DCP
Publicly available assessment report	

PRODUCT SUMMARY

EU procedure number	FR/V/0519/001/DC
Name, strength and pharmaceutical form	RILEXINE 150 MG/ML, powder and solvent for solution for injection for dogs and cats
Applicant	VIRBAC 1ère avenue 2065 M L I D 06516 CARROS cedex France
Active substance(s)	Cefalexin
ATC vetcode	QJ01DB01
Target species	Dogs and cats
Indication for use	Treatment of respiratory tract, uro-genital tract, skin and soft tissues infections

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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*	Application in accordance with Article 18 of Regulation (EC) 2019/6 as amended.
Reference product (RP)	RILEXINE POUDRE INJECTABLE 1 G
Marketing authorisation holder	VIRBAC 1ère avenue 2065 M L I D 06516 CARROS cedex France
Marketing authorisation number	FR/V/0912535 7/1992
EU procedure number	FR/V/0519/001/DC
Date of authorisation	30-06-1992

*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 reference ability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

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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 0,83 g/vial of cefalexin (as sodium) (*i.e* 150 mg/mL in the reconstituted solution) and the excipient water for injections.

The container/closure system consists of a powder glass vial and a solvent glass ampoule.

The choice of the formulation and the absence of 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.

C. Production and control of starting materials

The active substance is cefalexin sodium, an established active substance. 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 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.

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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.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence 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 / the environment / consumers.

A. Safety tests

Pharmacological studies

See part 4.

User safety

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

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 relevant VICH guideline 6.

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 (cats and dogs).

If used as recommended, the risk for the environment will be negligible.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with 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.

A. Pre-Clinical Studies

Pharmacology

The bioequivalence was demonstrated according to the section 7.1 of the bioequivalence GL (EMA/CVMP/016/2000-Rev4*) for all routes of administration (intravenous, intramuscular and subcutaneous), with support of pharmacodynamics/pharmacokinetics data.

Moreover, both cefalexine salts have similar physicochemical properties and high solubility.

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 cephalexin in relevant target bacteria per target animal species. Adequate warnings and precautions appear on the product literature.

Tolerance in the target species of animals

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with a reference VMP has been demonstrated, tolerance studies are not required. The tolerance profile of the candidate product should be the same as for the VMP.

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

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B. Clinical trials

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and bioequivalence with 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.