ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Versifel CVR

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Versifel CVR
Applicant	Zoetis UK Limited
Active substance(s)	Live attenuated feline enteritis (panleucopaenia) virus (FPV), Snow Leopard strain Live attenuated feline rhinotracheitis virus (FVR), strain FVRm Live attenuated Calicivirus (FCV), strain F9
ATC Vetcode	QI06AD04
Target species	Cats from 9 weeks of age
Indication for use	Active immunisation of cats to reduce mortality and clinical signs of disease caused by feline enteritis (panleucopaenia) virus, to reduce clinical signs of disease caused by feline rhinotracheitis virus and to prevent clinical signs of disease and reduce infection caused by feline calicivirus. Onset of immunity occurs by approximately 3 weeks after the last dose of the Basic Vaccination Scheme. The duration of immunity is at least 12 months.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Veterinary Medicines Directorate website (www.vmd.defra.gov.uk)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Full application in accordance with Article 12 of Directive 2001/82/EC as amended.

I. SCIENTIFIC OVERVIEW

The product is for active immunisation of cats to reduce mortality and clinical signs due to feline enteritis (panleucopaenia) virus, in order to reduce clinical signs caused by feline rhinotracheitis virus and to prevent clinical signs and reduce infection caused by feline calcivirus. The onset of immunity is approximately 3 weeks after the last dose of the Basic Vaccine Scheme.

This product was originally authorised under an Informed Consent legal basis but a variation was subsequently submitted to convert this to a Full marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The product contains live attenuated feline enteritis (panleucopaenia) virus (FPV), Snow Leopard strain, with a minimum titre of $10^{3.0}$ $CCID^{50}$, and live attenuated rhinotracheitis virus (FVR), strain FVRm, with a minimum titre of $10^{5.0}$ $CCID^{50}$. The excipients are neomycin and gentamycin.

The container/closure system consists of 25 Type I monodose glass vials each for both the lyophilisate and solvent components. Both vials have a rubber stopper and aluminium cap. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the vaccine strain, protocols, and presence of preservative are justified. The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substances are established active substances manufactured in accordance with the principles of good manufacturing practice. Starting

materials of non-biological origin used in production comply with relevant specifications.

Biological starting materials used are in compliance with the relevant Ph. Eur. Monographs and guidelines and are appropriately screened for the absence of extraneous agents according to the Guidelines, any deviation was adequately justified. The master and working seeds have been produced according to the Seed Lot System as described in the relevant guideline.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

Scientific data and certificates of suitability were provided in compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products.

E. Control tests during production

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

F. Control Tests on the Finished Product

The tests performed on the final product conform to the relevant requirements, any deviation from these requirements was justified.

G. Stability

Stability data on the active substances were provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions. The in-use shelf-life of the reconstituted vaccine is supported by the data provided.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

The shelf-life of the veterinary medicinal product as packaged for sale is 2 years. The product should be used immediately after reconstitution.

III. SAFETY ASSESSMENT

Laboratory trials

Suitable studies were performed for the original, parent product of Versifel CVR. There was no requirement to provide a public assessment report for the original product, therefore, no further data are provided here.

Field studies

Suitable studies were performed for the original, parent product of Versifel CVR. There was no requirement to provide a public assessment report for the original product, therefore, no further data are provided here.

Ecotoxicity

Suitable studies were performed for the original, parent product of Versifel CVR. There was no requirement to provide a public assessment report for the original product, therefore, no further data are provided here.

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

IV CLINICAL ASSESSMENT (EFFICACY)

Clinical Studies

Laboratory Trials

Suitable studies were performed for the original, parent product of Versifel CVR. There was no requirement to provide a public assessment report for the original product, therefore, no further data are provided here.

Field Trials

Suitable studies were performed for the original, parent product of Versifel CVR. There was no requirement to provide a public assessment report for the original product, therefore, no further data are provided here.

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 Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) 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.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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