

IPAR



Publicly Available Assessment Report for a Veterinary Medicinal Product

Fevaxyn Quatrifel Suspension for injection for cats

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Fevaxyn Quatrifel Suspension for injection for cats
Active substance(s)	Inactivated Feline Panleukopenia Virus (CU4 strain) Inactivated Feline Calicivirus (255 strain) Inactivated Feline Rhinotracheitis Virus (605 strain) Inactivated <i>Chlamydophila felis</i> (Cello strain)
Marketing authorisation holder	Zoetis Ireland Limited 25/28 North Wall Quay Dublin 1 Ireland
Marketing authorisation number	10438/054/001
Legal basis of application	Review application in accordance with Directive 90/677/EC
Date of authorisation	Renewal: 27 th June 2009
Indication and target species	Cats from 8 weeks of age
Method of sale and supply	POM
Additional supply restrictions	None

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA’s website.

I SCIENTIFIC OVERVIEW

The initial application for Fevaxyn Quatrifel Suspension for injection for cats was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available. Please refer to section VI for significant post-approval changes which are important for the quality, safety and efficacy of the product.

II QUALITY ASPECTS

See section I.

III SAFETY ASSESSMENT

See section I.

IV CLINICAL ASSESSMENT (EFFICACY)

See section I.

V OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

On the basis of the original data submitted, the HPRA considered that the product demonstrated adequate evidence of efficacy for the approved indications as well as a satisfactory benefit/risk profile and therefore granted a marketing authorisation.

VI 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 HPRA website.

This section 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.

Quality Changes

Summary of change (CRN 7006055)	Approval date
Data provided in this variation application demonstrated that replacement of Neocryl XK-62 in the Fevaxyn Quatrifel adjuvant system with Neocryl A640 did not alter the safety or efficacy profile of the vaccine. The official name for the <i>Chlamydia psittaci</i> active ingredient is now <i>Chlamydophila felis</i> , therefore it is appropriate that this is the name used in the SPC and Product Literature. These changes were considered satisfactory by the HPRA.	21/07/2009