European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
SUMMARY OF OPINION*
LEUCOFELIGEN FELV/RCP

On 11 March 2009, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the veterinary medicinal product Leucofeligen FeLV/RCP, a lyophilisate and solvent for suspension for injection for cats, intended for the active immunisation of cats against feline calicivirosis, feline viral rhinotracheitis, feline panleucopenia and feline leukaemia. The Applicant for this veterinary medicinal product is Virbac S.A..

The active substances of Leucofeligen FeLV/RCP are in the lyophilisate: live feline calicivirosis virus (strain F9), live feline viral rhinotracheitis virus (strain F2), live feline panleucopenia virus (strain LR 72), and in the solvent a minimum quantity of purified p45 FeLV (feline leukaemia virus) envelope antigen. Leucofeligen FeLV/RCP is a live and inactivated viral vaccine (ATCvet Code: QI06AH07).

The benefits of Leucofeligen FeLV/RCP are for feline calicivirosis the reduction of clinical signs, for feline viral rhinotracheitis the reduction of clinical signs and viral excretion, for feline panleucopenia the prevention of leucopenia and reduction of clinical signs, and for feline leukaemia the prevention of persistent viraemia and clinical signs of the related disease. The most common side effects are a moderate and transient local reaction (≤ 2cm) which can occur after the first injection but which resolves spontaneously within 3 to 4 weeks at the most. After the second injection, and subsequent administrations, this reaction is markedly reduced. In rare cases, pain at palpation, sneezing or conjunctivitis may occur which resolve without any treatment. Transient signs such as hyperthermia, apathy and digestive disturbances may also be observed following vaccination.

The approved indication is: "For active immunisation of cats from eight weeks of age against:

- feline calicivirosis to reduce clinical signs.
- feline viral rhinotracheitis to reduce clinical signs and viral excretion.
- feline panleucopenia to prevent leucopenia and to reduce clinical signs.
- feline leukaemia to prevent persistent viraemia and clinical signs of the related disease."

Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Leucofeligen FeLV/RCP and therefore recommends the granting of the marketing authorisation.

* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

** Applicants may appeal any CVMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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