1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LEUCOFELIGEN FeLV/RCP lyophilisate and suspension for suspension for injection for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 1 ml:

Lyophilisate:

Active substances:

Live attenuated feline calicivirus (strain F9)	$10^{4.6}$–$10^{6.1}$ $CCID_{50}$*
Live attenuated feline viral rhinotracheitis virus (strain F2)	$10^{5.0}$–$10^{6.6}$ $CCID_{50}$*
Live attenuated feline panleucopenia virus (strain LR 72)	$10^{3.7}$–$10^{4.5}$ $CCID_{50}$*

* Cell culture infectious dose 50%.

Suspension:

Active substance:

Minimum quantity of purified p45 FeLV-envelope antigen	102 µg

Adjuvants:

3% aluminium hydroxide gel expressed as mg Al^{3+}	1 mg
Purified extract of *Quillaja saponaria*	10 µg

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Gelatin
Potassium hydroxide
Lactose monohydrate
Glutamic acid
Potassium dihydrogen phosphate
Dipotassium phosphate
Water for injections
Sodium chloride
Disodium phosphate
Suspension:
Sodium chloride
Disodium phosphate
Potassium dihydrogen phosphate
Water for injections

Aluminium hydroxide gel

Visual appearance:
Lyophilisate: White color.
Suspension: Opalescent liquid.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

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.

Onset of immunity:
- 3 weeks after the first injection of primary vaccination for the calicivirus component
- 3 weeks after the primary vaccination for the panleucopenia and leukaemia components,
- 4 weeks after the primary vaccination for the rhinotracheitis virus component.

Duration of immunity:
After the primary vaccination course, the duration of immunity lasts for one year for all components.

Following a first booster vaccination one year after the primary vaccination course, a duration of immunity of 3 years has been demonstrated for the leukaemia component.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

Maternally derived antibodies, especially those against feline panleucopenia virus, can negatively influence the immune response to vaccination.

3.5 Special precautions for use

Special precautions for safe use in the target species:
De-worming at least 10 days prior to vaccination is recommended.
Only feline leukaemia virus (FeLV) negative cats should be vaccinated. Therefore, a test for presence of FeLV before vaccination is recommended.
The feline calicivirus and feline panleucopenia virus vaccine strains can spread. It has been demonstrated that this spread did not cause adverse reactions on non-vaccinated cats.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

3.6 Adverse events

Cats:

Common (1 to 10 animals / 100 animals treated):	Injection site reaction[1], Injection site swelling[1], Injection site oedema[1], Injection site nodule[1]. Hyperthermia[2,3], Apathy[3] Digestive tract disorder[3].
Rare (1 to 10 animals / 10,000 animals treated):	Injection site pain[4, 5], Sneezing[5], Conjunctivitis[5].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis[6]. Febrile limping syndrome reactions[7].

[1]A moderate and transient local reaction (≤2 cm) is observed after the first injection and resolves spontaneously within 3 to 4 weeks at the most. After the second injection, and subsequent administrations, this reaction is markedly reduced.
[2]Lasting 1 to 4 days.
[3]Transient signs.
[4]At palpation.
[5]This resolves without any treatment.
[6]In case of anaphylactic shock, appropriate symptomatic treatment should be administered.
[7]May occur very rarely in kittens, as reported in the literature after the use of any vaccine containing a Feline Calicivirus component.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Do not use in pregnant cats.
The use is not recommended during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

3.9 Administration routes and dosage

Subcutaneous use.

Reconstitute one dose of lyophilisate with one dose of suspension, shake gently and administer immediately.

Administer subcutaneously one dose (1ml) of the veterinary medicinal product according to the following regimen of vaccination.

Primary vaccination:
- first injection in kittens from 8 weeks of age
- second injection 3 or 4 weeks later.

Maternally derived antibodies, especially those against feline panleucopenia virus, can negatively influence the immune response to vaccination. In such cases where maternally derived antibodies are expected, a third injection may be appropriate from 15 weeks of age.

Re-vaccinations:
Following a first booster vaccination one year after the primary vaccination course, subsequent vaccinations can be performed at intervals of three years for the leukaemia component.
In this case, since annual revaccination is required for calicivirus, rhinotracheitis virus and panleucopenia virus components, a single dose of FELIGEN RCP can be used annually.

The vaccine can be used as a booster for kittens or cats previously vaccinated with FELIGEN RCP and LEUCOGEN separately.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse reactions were observed after an overdose administration (10 doses of lyophilisate and 2 doses of suspension) of the veterinary medicinal product other than those mentioned in section 3.6 except local reactions that can last longer (from 5 to 6 weeks at the most).

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI06AH07

Vaccine against feline viral rhinotracheitis, feline calicivirosis, feline panleucopenia and feline leukaemia.

The vaccine contains the purified p45 FeLV-envelope antigen, obtained by genetic recombination of the *E. coli* strain. The antigenic suspension is adjuvanted with an aluminium hydroxide gel and with a purified extract of *Quillaja saponaria*.

For the leukaemia component, protection against persistent viraemia is observed in 73% of cats 3 weeks after their first vaccine injection.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Lyophilisate:
A type I glass vial containing one dose of freeze-dried attenuated live viral components with a butyl elastomer stopper.

Suspension:
A type I glass vial containing one dose (1 ml) of the adjuvanted liquid vaccine, with a 13 mm-diameter butyl elastomer stopper and set with an aluminium capsule.

Plastic or cardboard box of 10 lyophilisate vials and 10 suspension vials.
Plastic or cardboard box of 50 lyophilisate vials and 50 suspension vials.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/09/097/001–002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 25/06/2009.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).