SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Leucogen suspension for injection for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substance:
Minimum quantity of purified feline leukemia virus, envelope P45 protein 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
Sodium chloride
Disodium phosphate
Potassium dihydrogen phosphate
Water for injections

Opalescent liquid.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

Active immunisation of cats from eight weeks of age against feline leukaemia for the prevention of persistent viraemia and clinical signs of the related disease.

Onset of immunity: 3 weeks after the primary vaccination.

Duration of immunity: One year after the primary vaccination course.

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

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

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.

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.

Special precautions for the protection of the environment:

Not applicable.

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]

[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.

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

Pregnancy and lactation:
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

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with FELIGEN CRP or FELIGEN RCP.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. A decision to use this vaccine before or after another veterinary medicinal product therefore needs to be made on a case by case basis.

3.9 Administration routes and dosage

Subcutaneous use.

Shake the vial gently and administer subcutaneously one dose (1 ml) of the veterinary medicinal product according to the following regimen of vaccination.

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

Maternally derived antibodies 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.

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

No adverse events were observed after a two-fold overdose administration 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: QI06AA01.

Vaccine against feline leukaemia.

The vaccine contains the purified feline leukemia virus, envelope P45 protein, 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*.

Protection against persistent viraemia is observed in 73% of cats 3 weeks after their first vaccine injection.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except FELIGEN RCP or FELIGEN CRP.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 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

Type I glass vials containing one dose (1 ml) of the vaccine closed with a 13 mm-diameter butyl elastomer stopper and aluminium capsule.

Plastic or cardboard box of 10 vials.
Plastic or cardboard box of 50 vials.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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

Vm 05653/5014

8. DATE OF FIRST AUTHORISATION

17 June 2009

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

May 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall
Approved: 27 May 2026