SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac LeuFel suspension for injection for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 1 ml:

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:
Buffered isotonic solution to 1 ml.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Opalescent liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Cats

4.2 Indications for use, specifying the 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.

The onset of immunity has been demonstrated from 3 weeks after the primary vaccination.

After the primary vaccination course, the duration of immunity lasts for one year.

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

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
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.

4.6 Adverse reactions (frequency and seriousness)

A moderate and transient local reaction (≤2 cm) is commonly observed after the first injection. This local reaction could be a swelling, an oedema or a nodule and resolves spontaneously within from 3 to 4 weeks at the most. After the second injection, and subsequent administrations, this reaction is markedly reduced.
The transient signs following vaccination such as hyperthermia (lasting 1 to 4 days), apathy and digestive disturbances (such as emesis and diarrhoea) may also be commonly observed.
Pain at palpation, sneezing or conjunctivitis may be noted in rare cases. This resolves without any treatment.
Anaphylactic reactions have been reported in very rare cases. In case of anaphylactic shock, appropriate symptomatic treatment should be administered.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse reactions were observed after an overdose administration (2 doses) of the veterinary medicinal product other than those mentioned in section 4.6 except local reactions that can last longer (from 5 to 6 weeks at the most).

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Felidae, inactivated viral vaccines for cats.
ATCvet code: QI06AA01.

Vaccine against 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*.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Disodium phosphate anhydrous
Potassium dihydrogen phosphate

Aluminium hydroxide gel
Quillaja saponaria
Water for injections

6.2 Major incompatibilities

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

6.3 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.

6.4 Special precautions for storage

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

6.5 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065 m LID
06516 Carros
France

8. MARKETING AUTHORISATION NUMBER

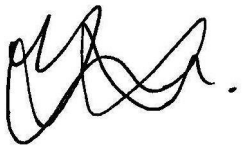
Vm 05653/5015

9. DATE OF FIRST AUTHORISATION

06 November 2017

10. DATE OF REVISION OF THE TEXT

September 2023



Approved: 20 September 2023