SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCT

Nobivac FeLV 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

Excipient

Buffered isotonic solution	to 1 ml

For a 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

- For active immunisation of healthy cats to prevent persistent feline leukaemia-virus viraemia and any associated clinical signs of the feline leucosis.
- The onset of protection begins 2 weeks after immunisation and the duration of protection lasts one year after the primo-vaccination.
- Following a first booster vaccination one year after the primary vaccination course, a duration of immunity of 3 years has been demonstrated.

4.3 Contra-indications

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

It is recommended that animals be treated for intestinal parasites at least 10 days prior to vaccination.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In the 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)

Transient and small thickening or nodule, approximately 5 - 10 mm in size, may be observed at the injection site and disappear within 2 to 6 weeks without treatment. Occasionally, systemic reactions (hyperthermia, anorexia, lethargy) may occur within one or two days after vaccine administration. Digestive disturbances (such as emesis and diarrhoea) may also be commonly observed.
Where Nobivac FeLV has been used to reconstitute cat vaccines in the Nobivac range containing feline calicivirus (F9 strain), feline rhinotracheitis virus (G2620A strain) and/or feline panleucopenia virus (MW-1 or Bristol strain) prior to inoculation, a small nodule at the site of vaccination is frequently observed. It can persist for up to 18 days post-inoculation. Occasionally, the nodule may be painful for up to 6 days after injection. A transient rise in body temperature or lameness may occur and last up to 3 days post vaccination. In some cases, a slight dullness or reduced appetite may be observed for up to 1 day post vaccination.
In the rare event of hypersensitivity reaction following vaccination, administer an antihistamine, corticosteroid or adrenaline without delay and by the most-immediate route.

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 cat vaccines of the Nobivac range containing feline calicivirus (F9 strain), feline rhinotracheitis virus (G2620A strain) and/or feline panleucopenia virus (MW-1 or Bristol strain).
Do not mix with other medicinal products except cat vaccines of the Nobivac range containing feline calicivirus (F9 strain), feline rhinotracheitis virus (G2620A strain) and/or feline panleucopenia virus (MW-1 or Bristol strain).
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

Shake the vial gently before use. Administer via the subcutaneous route 1 dose (1mL) of Nobivac FeLV according to the following regimen of vaccination.

Basic vaccination scheme
A first injection in cats from minimum 8 weeks of age.
A second injection of cats 3 to 4 weeks later.

Re-vaccination scheme
Following a first booster vaccination one year after the primary vaccination course, subsequent vaccinations can be performed at intervals of three years.

Nobivac FeLV can be used to reconstitute 1 dose (1 vial) of cat vaccines of the Nobivac range containing feline calicivirus (F9 strain), feline rhinotracheitis virus (G2620A strain) and/or feline panleucopenia virus (MW-1 or Bristol strain) immediately prior to use by the addition of the contents of one vial (1 ml) of Nobivac FeLV.

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

No undesirable effects have been seen after the administration of an overdose of Nobivac FeLV except those indicated in section 4.6. Adverse reactions (frequency and seriousness)

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: inactivated viral vaccine.
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 antigen 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
Quillaja saponaria
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal products except cat vaccines of the Nobivac range containing feline calicivirus (F9 strain), feline rhinotracheitis virus (G2620A strain) and/or feline panleucopenia virus (MW-1 or Bristol strain).

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 sunlight.

6.5 Nature and composition of immediate packaging

A type I glass vial containing one dose (1 ml) of the vaccine with a 13 mm-diameter butyl elastomer stopper and set with an aluminium capsule.
Cardboard or plastic box with 10 vials.
Cardboard or plastic box with 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 material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

8. MARKETING AUTHORISATION NUMBER

Vm 05653/4059

9. DATE OF FIRST AUTHORISATION

28 October 2005

10. DATE OF REVISION OF THE TEXT

August 2023

Approved 29 August 2023