ANNEX I

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:

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:
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.

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

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 reactions were observed after an overdose administration (2 doses) 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 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.

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 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/2/17/217/001-002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 06/11/2017.

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).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 10 or 50 vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac LeuFel suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 1 ml:
Minimum quantity of purified p45 FeLV-envelope antigen 102 µg

3. PACKAGE SIZE

10 x 1 ml
50 x 1 ml

4. TARGET SPECIES

Cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

EU/2/17/217/001 10 vials
EU/2/17/217/002 50 vials

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac LeuFel

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

102 µg FeLV
1 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy }

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nobivac LeuFel suspension for injection for cats

2. 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

Opalescent liquid.

3. Target species

Cats.

4. Indications for use

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:
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.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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.

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

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 and 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.

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

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

7. 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 (severe allergic reaction)[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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Subcutaneous use (under the skin).

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.

9. Advice on correct administration

Shake the vial gently before use.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label and the carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: use immediately.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/17/217/001-002

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

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

VIRBAC
1ère avenue 2065 m LID
06516 Carros Cedex
France

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

België/Belgique/Belgien
VIRBAC Belgium NV
Esperantolaan 4
BE-3001 Leuven
Tél/Tel: +32-(0)16 387 260
phv@virbac.be

Lietuva
VIRBAC
1ère avenue 2065 m LID
06516 Carros
Prancūzija
Tel: +33-(0)4 92 08 73 00

Република България
VIRBAC
1ère avenue 2065 m LID
06516 Carros
Франция
Тел: +33-(0)4 92 08 73 00

Česká republika
VIRBAC Czech Republic s.r.o.
Žitavského 496
156 00 Praha 5
Česká republika
Tel.: +420 608 836 529

Danmark
VIRBAC Danmark A/S
Profilvej 1
DK-6000 Kolding
Tlf: +45 75521244
virbac@virbac.dk

Deutschland
VIRBAC Tierarzneimittel GmbH
Rögen 20
DE-23843 Bad Oldesloe
Tel: +49-(4531) 805 111

Eesti
VIRBAC
1ère avenue 2065 m LID
06516 Carros
Prantsusmaa
Tel: +33-(0)4 92 08 73 00

Ελλάδα
VIRBAC ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.
13ο χλμ Ε.Ο. Αθηνών - Λαμίας
EL-14452, Μεταμόρφωση
Τηλ: +30 2106219520
info@virbac.gr

España
Merck Sharp & Dohme Animal Health, S.L.
POLÍGONO EL MONTALVO III
Calle Primera, 36
37188 Carbajosa de la Sagrada (Salamanca)
ESPAÑA
Tel: + 34 923 19 03 45

Luxembourg/Luxemburg
VIRBAC Belgium NV
Esperantolaan 4
BE-3001 Leuven
Belgique / Belgien
Tél/Tel: +32-(0)16 387 260
info@virbac.be

Magyarország
VIRBAC HUNGARY KFT
Váci utca 81. 4 emelet.
HU-1056 Budapest
Tel.: +36703387177
akos.csoman@virbac.hu

Malta
VIRBAC
1ère avenue 2065 m LID
06516 Carros
Franza
Tel: + 33-(0)4 92 08 73 00

Nederland
VIRBAC Nederland BV
Hermesweg 15
3771 ND-Barneveld
Tel : +31-(0)342 427 127
phv@virbac.nl

Norge
VIRBAC Danmark A/S
Profilvej 1
DK-6000 Kolding
Danmark
Tlf: + 45 75521244
virbac@virbac.dk

Österreich
VIRBAC Österreich GmbH
Hildebrandgasse 27
A-1180 Wien
Tel: +43-(0)1 21 834 260

Polska
VIRBAC Sp. z o.o.
ul. Puławska 314
PL 02-819 Warszawa
Tel.: + 48 22 855 40 46

France
Intervet
Rue Olivier de Serres
Angers Technopôle
49071 Beaucouzé Cedex
France
Tél: + 33 (0)2 41 22 83 83

Hrvatska
VIRBAC
1ère avenue 2065 m LID
FR-06516 Carros
Francuska
Tel: + 33-(0)4 92 08 73 00

Ireland
VIRBAC IRELAND
McInerney & Saunders
38, Main Street
Swords, Co Dublin
K67E0A2
Republic Of Ireland
Tel: +44 (0)-1359 243243

Ísland
VIRBAC
1ère avenue 2065 m LID
FR-06516 Carros
Frakkland
Tel: + 33-(0)4 92 08 73 00

Italia
VIRBAC SRL
Via Ettore Bugatti, 15
IT-20142 Milano
Tel: + 39 02 40 92 47 1

Κύπρος
VIRBAC ΕΛΛΑΣ ΜΟΝΟΠΡΟΣΩΠΗ Α.Ε.
13ο χλμ Ε.Ο. Αθηνών - Λαμίας
EL-14452, Μεταμόρφωση
Τηλ.: +30 2106219520
info@virbac.gr

Latvija
VIRBAC
1ère avenue 2065 m LID
FR-06516 Carros
Francija
Tel: +33-(0)4 92 08 73 00

Portugal
VIRBAC de Portugal Laboratórios LDA
Rua.do Centro Empresarial
Edif.13-Piso 1- Escrit.3
Quinta da Beloura
PT-2710-693 Sintra
Tel: + 351 219 245 020

România
VIRBAC
1ère avenue 2065 m LID
FR-06516 Carros
Franţa
Tel: + 33-(0)4 92 08 73 00

Slovenija
VIRBAC
1ère avenue 2065 m LID
FR-06516 Carros
FRANCIJA
Tel: + 33-(0)4 92 08 73 00

Slovenská republika
VIRBAC Czech Republic s.r.o.
Žitavského 496
156 00 Praha 5
Česká republika
Tel.: +420 608 836 529

Suomi/Finland
VIRBAC
1ère avenue 2065 m LID
FR-06516 Carros
Ranska
Puh/Tel: + 33-(0)4 92 08 73 00

Sverige
VIRBAC Danmark A/S Filial Sverige
Box 1027
SE-171 21 Solna
Tel: +45 75521244
virbac@virbac.dk

United Kingdom (Northern Ireland)
VIRBAC IRELAND
McInerney & Saunders
38, Main Street
Swords, Co Dublin
K67E0A2
Republic Of Ireland
Tel: +44 (0)-1359 243243

17. Other information

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