ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

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%.

Excipient:

Stabilizing buffer containing gelatin	to 1.3 ml before freeze-drying

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

Excipient:

Buffered isotonic solution to	1 ml.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and suspension for suspension for injection.

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

4. CLINICAL PARTICULARS

4.1 Target species

Cats

4.2 Indications for use, specifying the 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.

The onset of immunity has been demonstrated from:

- 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.

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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

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

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.
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.

4.6 Adverse reactions (frequency and seriousness)

A moderate and transient local reaction ($\leq$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 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.
Febrile limping syndrome reactions may occur very rarely in kittens, as reported in the literature after the use of any vaccine containing a Feline Calicivirus component.

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

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.

4.9 Amounts to be administered and administration route

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.

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

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 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, live and inactivated viral vaccines for cats.
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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Gelatin
Potassium hydroxide
Lactose monohydrate
Glutamic acid
Potassium dihydrogen phosphate
Dipotassium phosphate
Water for injections
Sodium chloride
Disodium phosphate anhydrous

Suspension:
Sodium chloride
Disodium phosphate anhydrous
Potassium dihydrogen phosphate
Aluminium hydroxide gel
Quillaja saponaria
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution: 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

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.

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(S)

EU/2/09/097/001–002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25/06/2009.
Date of last renewal: 06/06/2014.

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers of the biological active substances

PP MANUFACTURING CORPORATION
175 crossing Boulevard Suite 200,
Framingham,
Massachusetts 01702,
USA

VIRBAC
1ère avenue 2065 m LID
06516 Carros
FRANCE

Name and address of the manufacturer responsible for batch release

VIRBAC
1ère avenue 2065 m LID
06516 Carros
FRANCE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 10 or 50 lyophilisate vials and 10 or 50 suspension vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Lyophilisate and suspension for suspension for injection.

4. PACKAGE SIZE

10 x 1 dose
50 x 1 dose

5. TARGET SPECIES

Cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use
Subcutaneous use

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065 m LID
06516 Carros
FRANCE

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/09/097/001
EU/2/09/097/002

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LYOPHILISATE VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LEUCOFELIGEN FeLV/RCP, lyophilisate for cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

RCP

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SUSPENSION VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suspension for LEUCOFELIGEN FeLV/RCP, for cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

102 µg FeLV

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for the batch release:

VIRBAC
1ère avenue 2065 m LID
06516 Carros
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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%.

Excipient:

Stabilizing buffer containing gelatin: to	1.3 ml before freeze-drying

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

Excipient:

Buffered isotonic solution to	1 ml.

Visual aspect:
Lyophilisate: White pellet.
Suspension: Opalescent liquid.

4. INDICATION(S)

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.

The onset of immunity has been demonstrated from:
- 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 components.

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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 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.
Febrile limping syndrome reactions may occur very rarely in kittens, as reported in the literature after the use of any vaccine containing a Feline Calicivirus component.

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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 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.

9. ADVICE ON CORRECT ADMINISTRATION

Reconstitute one dose of lyophilisate with one dose (1ml) of suspension, shake gently and administer immediately.

10. WITHDRAWAL PERIOD(S)

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 after EXP.
Shelf life after reconstitution according to directions: use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

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

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.
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.

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:
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.

Overdose (symptoms, emergency procedures, 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 6 except local reactions that can last longer (from 5 to 6 weeks at the most).

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

15. OTHER INFORMATION

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

Suspension:
Type I glass vial containing one dose (1 ml) of the adjuvanted liquid, 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

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

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

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