ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LEUCOGEN 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 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*.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Disodium phosphate anhydrous
Potassium dihydrogen phosphate
Aluminium hydroxide
Quillaja saponaria

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product 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 – L.I.D.
06516 Carros Cedex
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/09/096/001–002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17/06/2009.
Date of last renewal: 12/06/2014.

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 AND USE

C. STATEMENT OF THE MRLs

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

Name and address of the manufacturer of the biological active substance

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

Name and address of the manufacturer responsible for batch release

Virbac
1ère avenue – 2065 m – L.I.D.,
06516 Carros Cedex
FRANCE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND 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 vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LEUCOGEN suspension for injection for cats

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 1 ml:

Active substance:
M
inimum quantity of purified p45 FeLV-envelope antigen: 102 µg

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

10 x 1 ml
50 x 1 ml

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 broached 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 the 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 – L.I.D.,
06516 Carros Cedex
FRANCE

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/09/096/001
EU/2/09/096/002

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

LEUCOGEN suspension for injection 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:
LEUCOGEN 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 – L.I.D.,
06516 Carros Cedex
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

LEUCOGEN suspension for injection for cats

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

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.

Opalescent liquid.

4. INDICATION(S)

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.

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.

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 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 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 first opening the container: use immediately.

12. SPECIAL WARNING(S)

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

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.

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 (symptoms, emergency procedures, antidotes):
No adverse reactions were observed after an overdose administration 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:
Do not mix with any other veterinary medicinal product except FELIGEN RCP or FELIGEN CRP.

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

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.

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

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