ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax FeLV suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 1 ml or 0.5 ml:

Active substance:
FeLV recombinant Canarypox virus (vCP97) $\geq 10^{7.2}$ $CCID_{50}$[1]

[1]cell culture infective dose 50%

Excipients:

Qualitative composition of excipients and other constituents
Potassium chloride
Sodium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Magnesium chloride hexahydrate
Calcium chloride dihydrate
Water for injections

Clear colourless liquid with presence of cell debris in suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

Active immunisation of cats of 8 weeks of age or older against feline leukaemia for the prevention of persistent viraemia and clinical signs of the related disease.

Onset of immunity: 2 weeks after primary vaccination course.
Duration of immunity: 1 year after the last vaccination.

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:
It is recommended that a test for FeLV antigenaemia be carried out prior to vaccination.
Vaccination of FeLV positive cats is of no benefit.

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:

Very common (>1 animal / 10 animals treated):	Injection site nodule.[1] Lethargy, hyperthermia.[2]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anorexia, emesis. Hypersensitivity reaction, anaphylaxis.[3]

[1] Small (< 2cm), regresses within 1 to 4 weeks.
[2] Lasting usually for 1 day, exceptionally for 2 days.
[3] If such reactions occur, appropriate treatment is recommended.

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 during the whole pregnancy and 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 with Boehringer Ingelheim non-adjuvanted vaccine range (various combinations of feline viral rhinotracheitis, calicivirosis, panleukopenia and chlamydiosis components) and/or administered the same day but not mixed with Boehringer Ingelheim adjuvanted vaccine against rabies.

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 any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

3.9 Administration routes and dosage

Subcutaneous use.
Shake well before use.

Administer one dose of 1 ml or 0.5 ml (depending on the presentation chosen) according to the following schedule:

Basic vaccination:	first injection: from 8 weeks of age, second injection: 3 to 5 weeks later.
Revaccination:	annual

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse events other than those already mentioned in section 3.6 “Adverse events” have been observed.

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: QI06AD07

The vaccine strain is a recombinant canarypox virus expressing the env and gag genes of FeLV-A. Under field conditions, only sub-group A is infective and immunisation against sub-group A provides full protection against A, B and C. After inoculation, the virus expresses the protective proteins, but does not replicate in the cat. As a consequence, the vaccine induces an immune status against feline leukaemia virus.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except those mentioned in section 3.8 above.

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).
Protect from light.
Do not freeze.

5.4 Nature and composition of immediate packaging

Type I glass bottle containing 1 ml or 0.5 ml of vaccine, closed with a butyl elastomer closure and sealed with an aluminium cap.

Plastic box containing 10, 20 or 50 bottles of 1 ml of vaccine.

Plastic box containing 10, 20 or 50 bottles of 0.5 ml of vaccine.

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

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/00/019/005-010

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 13/04/2000

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

Plastic box of 10 bottles of vaccine
Plastic box of 20 bottles of vaccine
Plastic box of 50 bottles of vaccine

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax FeLV suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 0.5 ml or 1 ml:
FeLV recombinant Canarypox virus (vCP97) $\geq 10^{7.2}$ $CCID_{50}$

3. PACKAGE SIZE

10 x 1 ml (10 x 1 dose)
20 x 1 ml (20 x 1 dose)
50 x 1 ml (50 x 1 dose)
10 x 0.5 ml (10 x 1 dose)
20 x 0.5 ml (20 x 1 dose)
50 x 0.5 ml (50 x 1 dose)

4. TARGET SPECIES

Cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

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

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

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

EU/2/00/019/005 10 x 1 ml (10 x 1 dose)
EU/2/00/019/006 20 x 1 ml (20 x 1 dose)
EU/2/00/019/007 50 x 1 ml (50 x 1 dose)
EU/2/00/019/008 10 x 0.5 ml (10 x 1 dose)
EU/2/00/019/009 20 x 0.5 ml (20 x 1 dose)
EU/2/00/019/010 50 x 0.5 ml (50 x 1 dose)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Suspension bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax FeLV

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

0.5 ml or 1 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Purevax FeLV suspension for injection

2. Composition

Per dose of 1 ml or 0.5 ml:

Active substances:
FeLV recombinant Canarypox virus (vCP97) $\geq 10^{7.2}$ $CCID_{50}$[1]

[1]cell culture infective dose 50%

Clear colourless liquid with presence of cell debris in suspension.

3. Target species

Cats.

4. Indications for use

Active immunisation of cats of 8 weeks of age or older against feline leukaemia for the prevention of persistent viraemia and clinical signs of the related disease.

Onset of immunity: 2 weeks after primary vaccination course.
Duration of immunity: 1 year after the last vaccination.

5. Contraindications

None.

6. Special warnings

Vaccinate healthy animals only.

Special precautions for safe use in the target species:
It is recommended that a test for FeLV antigenaemia be carried out prior to vaccination.
Vaccination of FeLV positive cats is of no benefit.

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 during the whole pregnancy and 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 with Boehringer Ingelheim non-adjuvanted vaccine range (various combinations of feline viral rhinotracheitis, calicivirosis, panleukopenia and chlamydiosis components) and/or administered the same day but not mixed with Boehringer Ingelheim adjuvanted vaccine against rabies.
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 any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

Overdose:
No adverse events other than those already mentioned in section "Adverse events" have been observed.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except those mentioned above.

7. Adverse events

Cats:

Very common (>1 animal / 10 animals treated):
Injection site nodule.[1]
Lethargy, hyperthermia.[2]

Very rare (<1 animal / 10 000 animals treated, including isolated reports):
Anorexia, emesis.
Hypersensitivity reaction, anaphylaxis.[3]

[1] Small (< 2 cm) , regresses within 1 to 4 weeks.
[2] Lasting usually for 1 day, exceptionally for 2 days.
[3] If such reactions occur, appropriate treatment is recommended.

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.

Administer one dose of 1 ml or 0.5 ml of vaccine (depending on the presentation chosen) according to the following schedule:

Basic vaccination:	first injection: from 8 weeks of age, second injection: 3 to 5 weeks later.
Revaccination:	annual

9. Advice on correct administration

Shake well 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).
Protect from light.
Do not freeze.
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 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/00/019/005-010

Plastic box containing:
10, 20 or 50 x 1 ml of vaccine or
10, 20 or 50 x 0.5 ml of vaccine.

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:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint-Priest
France

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien
Boehringer Ingelheim Animal
Health Belgium SA
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1050 Bruxelles/Brussel/Brüssel
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17. Other information

Vaccine against feline leukaemia.

The vaccine strain is a recombinant canarypox virus expressing the *env* and *gag* genes of FeLV-A. Under field conditions, only sub-group A is infective and immunisation against sub-group A provides full protection against A, B and C. After inoculation, the virus expresses the protective proteins, but does not replicate in the cat. As a consequence, the vaccine induces an immune status against feline leukaemia virus.