ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RCP FeLV lyophilisate and solvent for suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 1 ml or 0.5 ml:

Active substances:

Lyophilisate:

Attenuated feline rhinotracheitis herpesvirus (FHV F2 strain)	$\geq 10^{4.9}$ $CCID_{50}$[1]
Inactivated feline calicivirus (FCV 431 and FCV G1 strains) antigens	≥ 2.0 ELISA U.
Attenuated feline panleucopenia virus (PLI IV)	$\geq 10^{3.5}$ $CCID_{50}$[1]

Solvent:

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
Lyophilisate:
Sucrose
Sorbitol
Dextran 40
Casein hydrolysate
Collagen hydrolysate
Dipotassium phosphate
Potassium dihydrogen phosphate
Potassium hydroxide
Water for injections
Solvent:
Potassium chloride
Sodium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Magnesium chloride hexahydrate
Calcium chloride dihydrate
Water for injections

Lyophilisate: friable pellet, homogeneous from beige to white.

Solvent: 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 aged 8 weeks and older:
- against feline viral rhinotracheitis to reduce clinical signs,
- against calicivirus infection to reduce clinical signs,
- against feline panleucopenia to prevent mortality and clinical signs,
- against leukaemia to prevent persistent viraemia and clinical signs of the related disease.

Onset of immunity:
- Rhinotracheitis, calicivirus and panleucopenia components: 1 week after primary vaccination course.
- Feline leukaemia component: 2 weeks after primary vaccination course.

Duration of immunity:
- Rhinotracheitis, calicivirosis and panleucopenia components: 1 year after primary vaccination course and 3 years after the last re-vaccination.
- Feline leukaemia component: 1 year after the last re-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:

Common (1 to 10 animals / 100 animals treated):	Apathy, anorexia, hyperthermia[1]. Injection site reactions (pain, itching, oedema)[2].
Uncommon (1 to 10 animals / 1 000 animals treated):	Hypersensitivity reaction[3].
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Emesis[4].

[1] lasting usually for 1 or 2 days.
[2] slight pain at palpation, itching or limited oedema disappearing within 1 or 2 weeks at most.
[3] may require appropriate symptomatic treatment.
[4] mostly within 24 to 48 hours.

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 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.

Reconstitute gently the vaccine in order to obtain a uniform suspension with limited foam formation. Visual appearance after reconstitution: slightly yellow suspension with presence of cell debris in suspension.

After reconstitution of the lyophilisate with 0.5 ml or 1 ml of the solvent (depending on the presentation chosen) inject one dose of vaccine according to the following vaccination scheme:

Primary vaccination course:
- first injection: from 8 weeks of age,
- second injection: 3 to 4 weeks later.

Where high levels of maternal antibodies against rhinotracheitis, calicivirosis or panleucopenia components are expected to be present (e.g. in kittens of 9 to 12 weeks of age born from queens, which were vaccinated before pregnancy and/or with known or suspected previous exposure to the pathogen(s)), the primary vaccination course should be delayed until 12 weeks of age.

Revaccination:
- the first revaccination must be carried out for all components one year after the primary vaccination course,

Subsequent revaccinations:
- Feline leukaemia component: every year.
- Rhinotracheitis, calicivirosis and panleucopenia components: at intervals of up to three years.

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, except hyperthermia that may exceptionally last 5 days.

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: QI06AH10

Vaccine against feline viral rhinotracheitis, feline calicivirosis, feline panleucopenia and feline leukaemia.

Stimulates active immunity against feline rhinotracheitis virus, feline calicivirus, feline panleucopenia virus and feline leukaemia virus.

The veterinary medicinal product was shown to reduce excretion of feline calicivirus at onset of immunity and for one year after vaccination.

The feline leukaemia 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 the solvent supplied for use with the veterinary medicinal product and except those mentioned in section 3.8 above.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after reconstitution according to directions: 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 dose of lyophilisate and type I glass bottle containing 0.5 ml or 1 ml solvent, both closed with a butyl elastomer closure and sealed with an aluminium cap.

Plastic box containing 10 bottles of 1 dose of lyophilisate and 10 bottles of 1 ml of solvent.
Plastic box containing 50 bottles of 1 dose of lyophilisate and 50 bottles of 1 ml of solvent.
Plastic box containing 10 bottles of 1 dose of lyophilisate and 10 bottles of 0.5 ml of solvent.
Plastic box containing 50 bottles of 1 dose of lyophilisate and 50 bottles of 0.5 ml of solvent.

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/2/04/048/001-004

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 23/02/2005

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 lyophilisate and 10 bottles of solvent
Plastic box of 50 bottles of lyophilisate and 50 bottles of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RCP FeLV lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 0.5 ml or 1 ml:

FHV (F2 strain)	$\geq 10^{4.9}$ $CCID_{50}$
FCV (431 and G1 strains)	≥ 2.0 ELISA U.
FPV (PLI IV)	$\geq 10^{3.5}$ $CCID_{50}$
FeLV recombinant canarypox virus (vCP97)	$\geq 10^{7.2}$ $CCID_{50}$

3. PACKAGE SIZE

Lyophilisate (10 x 1 dose) + solvent (10 x 1 ml)
Lyophilisate (50 x 1 dose) + solvent (50 x 1 ml)
Lyophilisate (10 x 1 dose) + solvent (10 x 0.5 ml)
Lyophilisate (50 x 1 dose) + solvent (50 x 0.5 ml

4. TARGET SPECIES

Cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.{dd/mm/yyyy}
Once reconstituted 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/2/04/048/001 Lyophilisate (10 x 1 dose) + solvent (10 x 1 ml)
EU/2/04/048/002 Lyophilisate (50 x 1 dose) + solvent (50 x 1 ml)
EU/2/04/048/003 Lyophilisate (10 x 1 dose) + solvent (10 x 0.5 ml)
EU/2/04/048/004 Lyophilisate (50 x 1 dose) + solvent (50 x 0.5 ml)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RCP FeLV

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 dose
0.5 ml or 1 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Solvent bottle

1. NAME OF THE SOLVENT

Purevax RCP FeLV solvent

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 RCP FeLV lyophilisate and solvent for suspension for injection

2. Composition

Per dose of 1 ml or 0.5 ml:

Active substances:
Lyophilisate:

Attenuated feline rhinotracheitis herpesvirus (FHV F2 strain)	$\geq 10^{4.9}$ $CCID_{50}$[1]
Inactivated feline calicivirus (FCV 431 and FCV G1 strains) antigens	≥ 2.0 ELISA U.
Attenuated feline panleucopenia virus (PLI IV)	$\geq 10^{3.5}$ $CCID_{50}$[1]

Solvent:

FeLV recombinant canarypox virus (vCP97)	$\geq 10^{7.2}$ $CCID_{50}$[1]

[1] cell culture infective dose 50%

Lyophilisate: friable pellet, homogeneous from beige to white.
Solvent: clear colourless liquid with presence of cell debris in suspension.

3. Target species

Cats.

4. Indications for use

Active immunisation of cats aged 8 weeks and older:
- against feline viral rhinotracheitis to reduce clinical signs,
- against calicivirus infection to reduce clinical signs,
- against feline panleucopenia to prevent mortality and clinical signs,
- against leukaemia to prevent persistent viraemia and clinical signs of the related disease.

Onset of immunity:
- Rhinotracheitis, calicivirus and panleucopenia components: 1 week after primary vaccination course.
- Feline leukaemia component: 2 weeks after primary vaccination course.

Duration of immunity:
- Rhinotracheitis, calicivirosis and panleucopenia components: 1 year after primary vaccination course and 3 years after the last re-vaccination.
- Feline leukaemia component: 1 year after the last re-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 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 event other than those already mentioned in section on "Adverse events" have been observed, except hyperthermia that may exceptionally last 5 days.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the veterinary medicinal product and except those mentioned above.

7. Adverse events

Cats:

Common (1 to 10 animals / 100 animals treated):
Apathy, anorexia, hyperthermia[1].

Injection site reactions (pain, itching, oedema)[2].
Uncommon (1 to 10 animals / 1 000 animals treated):
Hypersensitivity reaction[3].

Very rare (<1 animal / 10 000 animals treated, including isolated reports):
Emesis[4].

[1] lasting usually for 1 or 2 days.

[2] slight pain at palpation, itching or limited oedema disappearing within 1 or 2 weeks at most.
[3] may require appropriate symptomatic treatment.
[4] mostly within 24 to 48 hours.

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.

After reconstitution of the lyophilisate with 0.5 ml or 1 ml of the solvent (depending on the presentation chosen) inject one dose of vaccine according to the following vaccination scheme:

Primary vaccination course:
- first injection: from 8 weeks of age.
- second injection: 3 to 4 weeks later.

Where high levels of maternal antibodies against rhinotracheitis, calicivirosis or panleucopenia components are expected to be present (e.g. in kittens of 9 to 12 weeks of age born from queens which were vaccinated before pregnancy and/or with known or suspected previous exposure to the pathogen(s)), the primary vaccination course should be delayed until 12 weeks of age.

Revaccination:
- the first revaccination must be carried out for all components one year after the primary vaccination course.

Subsequent revaccinations:
- Feline leukaemia component: every year.
- Rhinotracheitis, calicivirosis and panleucopenia components: at intervals of up to three years.

9. Advice on correct administration

Reconstitute gently the vaccine in order to obtain a uniform suspension with limited foam formation.
Visual appearance after reconstitution: slightly yellow suspension with presence of cell debris in suspension.

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 carton and the bottle after Exp.
Shelf life after reconstitution according to directions: 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/2/04/048/001-004

Plastic box containing:
10 x 1 dose of lyophilisate and 10 x 1 ml of solvent or
50 x 1 dose of lyophilisate and 50 x 1 ml of solvent or
10 x 1 dose of lyophilisate and 10 x 0.5 ml of solvent or
50 x 1 dose of lyophilisate and 50 x 0.5 ml of solvent.

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
Avenue Arnaud Fraiteurlaan 15-23,
1050 Bruxelles/Brussel/Brüssel
Tél/Tel: + 32 2 773 34 56

Lietuva
Boehringer Ingelheim RCV GmbH & Co KG
Lietuvos filialas
Dr. Boehringer Gasse 5-11
A-1121 Vīne, Austrija
Tel: +370 5 2595942

Република България
Boehringer Ingelheim RCV GmbH & Co KG
Dr. Boehringer Gasse 5-11
A-1121 Виена, Австрия
Tel: +359 2 958 79 98

Česká republika
Boehringer Ingelheim spol. s r.o.
Purkyňova 2121/3
CZ - 110 00, Praha 1
Tel: +420 234 655 111

Danmark
Boehringer Ingelheim Animal Health Nordics A/S
Weidekampsgade 14
DK-2300 København S
Tlf: + 45 3915 8888

Deutschland
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Tel: 0800 290 0 270

Eesti
Boehringer Ingelheim RCV GmbH & Co KG
Eesti filiaal
Dr. Boehringer Gasse 5-11
A-1121 Viin, Austria
Tel: +372 612 8000

Ελλάδα
Boehringer Ingelheim Vetmedica GmbH
D-55216 Ingelheim/Rhein, Γερμανία
Τηλ: +30 2108906300

España
Boehringer Ingelheim Animal Health España, S.A.U.
Prat de la Riba, 50
08174 Sant Cugat del Vallès (Barcelona)
Tel: +34 93 404 51 00

Luxembourg/Luxemburg
Boehringer Ingelheim Animal Health Belgium SA
Avenue Arnaud Fraiteurlaan 15-23,
1050 Bruxelles/Brussel/Brüssel
Tél/Tel: + 32 2 773 34 56

Magyarország
Boehringer Ingelheim RCV GmbH & Co KG
Magyarországi Fióktelep
Lechner Ö. Fasor 10.
H-1095 Budapest
Tel: +36 1 299 8900

Malta
Boehringer Ingelheim Vetmedica GmbH
D-55216 Ingelheim/Rhein, il-Ġermanja
Tel: +353 1 291 3985

Nederland
Boehringer Ingelheim Animal Health Netherlands bv
Basisweg 10
1043 AP Amsterdam
Tel: +31 20 799 6950

Norge
Boehringer Ingelheim Animal Health Nordics A/S
Weidekampsgade 14
DK-2300 København S
Tlf: +47 66 85 05 70

Österreich
Boehringer Ingelheim RCV GmbH & Co KG
Dr. Boehringer Gasse 5-11
A-1121 Wien
Tel: +43 1 80105-6880

Polska
Boehringer Ingelheim Sp. z o.o.
ul. Józefa Piusa Dziekońskiego 3
00-728 Warszawa
Tel.: + 48 22 699 0 699

France
Boehringer Ingelheim Animal Health France, SCS
29, avenue Tony Garnier
69007 Lyon
Tél : +33 4 72 72 30 00

Hrvatska
Boehringer Ingelheim RCV GmbH & Co KG
Dr. Boehringer Gasse 5-11
A-1121 Beč, Austrija
Tel: +385 1 2444 600

Ireland
Boehringer Ingelheim Vetmedica GmbH
D-55216 Ingelheim/Rhein, Germany
Tel: +353 1 291 3985

Ísland
Vistor
Hörgatún 2
210 Garðabær
Sími: + 354 535 7000

Italia
Boehringer Ingelheim Animal Health Italia S.p.A.
Via Vezza d'Oglio, 3
20139 Milano
Tel: +39 02 53551

Κύπρος
Boehringer Ingelheim Vetmedica GmbH
D-55216 Ingelheim/Rhein, Γερμανία
Τηλ: +30 2108906300

Latvija
Boehringer Ingelheim RCV GmbH & Co KG
Latvijas filiāle
Dr. Boehringer Gasse 5-11
A-1121 Viena, Austrija
Tel: +371 67 240 011

Portugal
Boehringer Ingelheim Animal Health Portugal, Unipessoal, Lda.
Avenida de Pádua, 11
1800-294 Lisboa
Tel: +351 21 313 5300

România
Boehringer Ingelheim RCV GmbH & Co KG
Sucursala Bucureşti
Dr. Boehringer Gasse 5-11
A-1121 Viena, Austria
Tel: +40 21 302 28 00

Slovenija
Boehringer Ingelheim RCV GmbH & Co KG
Podružnica Ljubljana
Dr. Boehringer Gasse 5-11
A-1121 Dunaj, Avstrija
Tel: +386 1 586 40 00

Slovenská republika
Boehringer Ingelheim RCV GmbH & Co KG, o.z.
Dr. Boehringer Gasse 5-11
A-1121 Viedeň, Rakúsko
Tel: +421 2 5810 1211

Suomi/Finland
Vetcare Oy
PL/PB 99
24101 Salo
Puh/Tel: + 358 201443360

Sverige
Boehringer Ingelheim Animal Health Nordics A/S
Weidekampsgade 14
DK-2300 København S
Tel: +46 (0)40-23 34 00

United Kingdom (Northern Ireland)
Boehringer Ingelheim Vetmedica GmbH
D-55216 Ingelheim/Rhein, Germany
Tel: +353 1 291 3985

17. Other information

The feline leukaemia 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.
The product was shown to reduce excretion of feline calicivirus at onset of immunity and for one year after vaccination.