ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RC lyophilisate and solvent for suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 1 ml or 0.5 ml:

Active substances:

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

[1] cell culture infective dose 50%

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Lyophilisate:	
Sucrose	
Sorbitol	
Dextran 40	
Casein hydrolysate	
Collagen hydrolysate	
Dipotassium phosphate	
Potassium dihydrogen phosphate	
Potassium hydroxide	
Sodium chloride	
Disodium hydrogen orthophosphate	
Monopotassium phosphate anhydrous	
Water for injections	
Solvent:	
Water for injections	*q.s. 1 ml or 0.5 ml*

Lyophilisate: homogeneous beige pellet.
Solvent: clear colourless liquid.

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.

Onset of immunity: 1 week after primary vaccination course.
Duration of immunity: 1 year after primary vaccination course and 3 years 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:
None.

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, and 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 section “Contact details” of the package leaflet.

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 and administered with Boehringer Ingelheim non-adjuvanted vaccine against feline leukaemia and/or administered the same day but not mixed with Boehringer Ingelheim adjuvanted vaccine against rabies.
Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Boehringer Ingelheim non-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 route.

Reconstitute gently the vaccine in order to obtain a uniform suspension with limited foam formation.
Visual appearance after reconstitution: clear slightly yellow 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 or calicivirosis 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 one year after the primary vaccination course,
- subsequent revaccinations: at intervals of up to three years.

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

No adverse event 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

None.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI06AH08.

Vaccine against feline viral rhinotracheitis and feline calicivirosis.
Stimulates active immunity against feline rhinotracheitis herpesvirus and feline calicivirus.
The veterinary medicinal product was shown to reduce excretion of feline calicivirus at onset of immunity and for one year after vaccination.

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 1 ml or 0.5 ml of solvent, both closed with a butyl elastomer closure and sealed with an aluminium or plastic 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 product 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/2/04/051/001-004

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RC lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 1 ml or 0.5 ml:
FHV (F2 strain) $\geq 10^{4.9}$ $CCID_{50}$
FCV (431 and G1 strains) ≥ 2.0 ELISA U.

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/2/04/051/001 Lyophilisate (10 x 1 dose) + solvent (10 x 1 ml)
EU/2/04/051/002 Lyophilisate (50 x 1 dose) + solvent (50 x 1 ml)
EU/2/04/051/003 Lyophilisate (10 x 1 dose) + solvent (10 x 0.5 ml)
EU/2/04/051/004 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 RC 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 dose
1 ml or 0.5 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 RC solvent 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 ml or 0.5 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 RC 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.

Solvent:

Water for injections	q.s. 1 ml or 0.5 ml.

[1] cell culture infective dose 50%.

Lyophilisate: homogeneous beige pellet.
Solvent: clear colourless liquid.

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.

Onset of immunity: 1 week after primary vaccination course.
Duration of immunity: 1 year after primary vaccination course and 3 years after the last re-vaccination.

5. Contraindications

None.

6. Special warnings

Vaccinate healthy animals only.

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 and administered with Boehringer Ingelheim non-adjuvanted vaccine against feline leukaemia and/or administered the same day but not mixed with Boehringer Ingelheim adjuvanted vaccine against rabies.
Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Boehringer Ingelheim non-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 "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 in section "Interaction with other medicinal products and other forms of interaction" above.

7. Adverse events

Cats:

- Common (1 to 10 animals / 100 animals treated): Apathy, anorexia, and 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] which 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.

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

Subcutaneous route.

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 or calicivirosis 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 one year after the primary vaccination course,
- subsequent revaccinations: 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: clear slightly yellow 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/2/04/051/001-004

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

Manufacturing authorisation holder 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
Tél/Tel: + 32 2 773 34 56

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Deutschland
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Lietuva
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Luxembourg/Luxemburg
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United Kingdom (Northern Ireland)
Boehringer Ingelheim Animal Health UK Limited
Tel: + 44 1344 746957

17. Other information

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