ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax Rabies suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substance:
Rabies recombinant canarypox virus (vCP65) $\geq 10^{6.8}$ FAID*$_{50}$
*Fluorescent assay infectious 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

Light pink to pale yellow homogeneous suspension

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

Active immunisation of cats 12 weeks of age and older to prevent mortality due to rabies infection.

Onset of immunity: 4 weeks after the primary vaccination course.
Duration of immunity after primary vaccination: 1 year.
Duration of immunity after revaccination: 3 years.

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:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Canarypox recombinants are known to be safe for humans. Mild local and/or systemic adverse reactions related to the injection itself may be observed transitorily.
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 rare (<1 animal / 10 000 animals treated, including isolated reports):	Apathy[1-2], mild anorexia[2], hyperthermia[2-3] Injection site reactions (pain, swelling, warmth and erythema)[4] Hypersensitivity reaction[5]

[1] Slight
[2] Usually lasting 1 or 2 days. Most of these reactions were noted during the 2 days following the vaccine injection.
[3] Above 39.5 °C
[4] Pain at palpation; limited swelling that may become nodular; usually disappearing within 1 or 2 weeks at most.
[5] Which may require appropriate symptomatic treatment

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 also section “Contact details” of the package leaflet.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Efficacy data are available which demonstrate that this vaccine can be administered at least 14 days before or after the administration of Boehringer Ingelheim non-adjuvanted vaccine against feline leukaemia.

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Boehringer Ingelheim non-adjuvanted vaccines containing various combinations of feline viral rhinotracheitis, calicivirosis, panleukopenia and chlamydiosis components.

3.9 Administration routes and dosage

Subcutaneous use.

Apply usual aseptic procedures.

Administer one dose of 1 ml according to the following vaccination scheme:

Primary vaccination: 1 injection from 12 weeks of age.
Revaccination: 1 year after primary vaccination, then at intervals of up to 3 years.

Travel to countries requiring a rabies serology test: experience has shown that some vaccinated animals, while protected, may not show the 0.5 IU/ml antibody titre required by some countries. Veterinary surgeons may wish to consider two vaccinations. The best time for a blood sample to be taken is around 28 days after vaccination.

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

No adverse events other than those already mentioned in section 3.6 have been observed after the administration of 10 doses. The reactions may last longer.

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

Official control authority batch release is required for this product.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATC vet code: QI06AD08

The vaccine strain vCP65 is a recombinant Canarypox virus expressing the glycoprotein G gene of rabies virus. After inoculation, the virus expresses the protective protein, but does not replicate in the cat. As a consequence, the vaccine stimulates active immunity against rabies virus in cats.

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: 18 months.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Type I glass vial of 1 ml (1 dose) with a butyl elastomer closure, sealed with an aluminium cap.
Cardboard box of 2 x 1 ml.
Plastic box of 10 x 1 ml or 50 x 1 ml.

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/2/10/117/001-003

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 18/02/2011

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 vials of suspension for injection
Plastic box of 50 vials of suspension for injection
Cardboard box of 2 vials of suspension for injection

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax Rabies suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (1 ml) contains:
Rabies recombinant canarypox virus (vCP65) $\geq 10^{6.8}$ $FAID_{50}$

3. PACKAGE SIZE

10 x 1 ml
50 x 1 ml
2 x 1 ml

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/2/10/117/001 (10 vials)
EU/2/10/117/002 (50 vials)
EU/2/10/117/003 (2 vials)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDATE PACKAGING UNITS

Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax Rabies 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 dose

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 Rabies suspension for injection

2. Composition

Each dose of 1 ml contains:

Active substance:
Rabies recombinant canarypox virus (vCP65) $\geq 10^{6.8}$ FAID*$_{50}$
*Fluorescent assay infectious dose 50 %

Light pink to pale yellow homogeneous suspension

3. Target species

Cats.

4. Indications for use

Active immunisation of cats 12 weeks of age and older to prevent mortality due to rabies infection.

Onset of immunity: 4 weeks after the primary vaccination course.
Duration of immunity after primary vaccination: 1 year.
Duration of immunity after revaccination: 3 years.

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:
Canarypox recombinants are known to be safe for humans. Mild local and/or systemic adverse reactions related to the injection itself may be observed transitorily.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Efficacy data are available which demonstrate that this vaccine can be administered at least 14 days before or after the administration of Boehringer Ingelheim non-adjuvanted vaccine against feline leukaemia.

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Boehringer Ingelheim non-adjuvanted vaccines containing various combinations of feline viral rhinotracheitis, calicivirosis, panleukopenia and chlamydiosis components.

Overdose:
No adverse events other than those already mentioned in the section "Adverse Events" have been observed after the administration of 10 doses. The reactions may last longer.

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

7. Adverse events

Cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports): Apathy[1-2], mild anorexia[2], hyperthermia[2-3]
Injection site reactions (pain, swelling, warmth and erythema)[4]
Hypersensitivity reaction[5]

[1] Slight
[2] Usually lasting 1 or 2 days. Most of these reactions were noted during the 2 days following the vaccine injection.
[3] Above 39.5 °C
[4] Pain at palpation; limited swelling that may become nodular; usually disappearing within 1 or 2 weeks at most.
[5] Which may require appropriate symptomatic treatment

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 according to the following vaccination scheme:

Primary vaccination course:	1 injection from 12 weeks of age,
Revaccination:	1 year after primary vaccination, then at intervals of up to 3 years.

Travel to countries requiring a rabies serology test: experience has shown that some vaccinated animals, while protected, may not show the 0.5 IU/ml antibody titre required by some countries. Veterinary surgeons may wish to consider two vaccinations. The best time for a blood sample to be taken is around 28 days after vaccination.

9. Advice on correct administration

Apply usual aseptic procedures.

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/2/10/117/001-003

Pack sizes:
Plastic box of 10 vials of 1 dose.
Plastic box of 50 vials of 1 dose.
Cardboard box of 2 vials of 1 dose.

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

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17. Other information

Vaccine against rabies infection.

The vaccine strain vCP65 is a recombinant Canarypox virus expressing the glycoprotein G gene of rabies virus. After inoculation, the virus expresses the protective protein, but does not replicate in the cat. As a consequence, the vaccine stimulates active immunity against rabies virus in cats.