ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RCCh lyophilisate and solvent for suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 1 ml

Lyophilisate:
Active substances:
Attenuated feline rhinotracheitis herpesvirus (FHV F2 strain) ..... $\geq 10^{4.9}$ $CCID_{50}$[1]
Inactivated feline Calicivirosis antigens (FCV 431 and G1 strains) ..... ≥ 2.0 ELISA U.
Attenuated *Chlamydophila felis* (905 strain) ..... $\geq 10^{3.0}$ EID_{50}[2]
Excipient:
Gentamicin, at most..... 28 µg

Solvent:
Water for injection .....q.s. 1 ml

[1]: cell culture infective dose 50%
[2]: egg infective dose 50%

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 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 and excretion,
- *against Chlamydophila felis* infection to reduce clinical signs.

Onsets of immunity have been demonstrated 1 week after primary vaccination course for rhinotracheitis, calicivirus and *Chlamydophila felis* components.

The duration of immunity is 1 year after the last (re-)vaccination.

4.3 Contraindications

Do not use in pregnant animals.
The use is not recommended during lactation.

4.4 Special warnings

None.

4.5 Special precautions for use

Special precautions for use in animals

Use only in healthy animals.

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.
This vaccine should not be handled by persons who are immunodeficient or taking immunosuppressive medicinal products. If self-injection occurs, immediate medical advice should be sought and the doctor informed that self-injection with a living chlamydial vaccine has occurred.

4.6 Adverse reactions (frequency and seriousness)

In normal conditions of use, transient apathy and anorexia may occasionally occur, as well as hyperthermia (lasting usually for 1 or 2 days). A local reaction may occur (slight pain at palpation, itching or limited oedema) that disappears within 1 or 2 weeks at most.
In exceptional circumstances a hypersensitivity reaction may occur, which may require appropriate symptomatic treatment.
In very rare cases, hyperthermia and lethargy sometimes associated with lameness has been observed one to three weeks following booster vaccination in adult cats. The reaction was transient

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant animals.
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 with Merial non-adjuvanted vaccine against feline leukaemia and/or administered the same day but not mixed with Merial adjuvanted vaccine against rabies.

4.9 Amounts to be administered and administration route

Inject by subcutaneous route one dose (1 ml) of vaccine after reconstitution of the lyophilisate with the solvent, 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 R, C or Ch components are expected to be present (e.g. in kittens of 9-12 weeks of age borne 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: every year.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No effect other than those already mentioned in section 4.6 “Adverse reactions” have been observed, except hyperthermia that may exceptionally last 5 days.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

ATC Vet code: QI06AJ02

Vaccine against feline viral rhinotracheitis, feline calicivirosis and chlamydiosis.
Stimulates active immunity against feline rhinotracheitis herpesvirus, feline calicivirus and *Chlamydophila felis*.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Sorbitol
Dextran 40
Casein hydrolysate
Collagen hydrolysate
Dipotassium phosphate
Potassium dihydrogen phosphate
Potassium hydroxide
Sodium chloride
Disodium hydrogen orthophosphate
Monopotassium phosphate anhydrous

6.2 Incompatibilities

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administrated with Merial non-adjuvanted vaccine against feline leukaemia

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:18 months.
Shelf life after reconstitution: use immediately after reconstitution

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Type I glass bottle containing 1 dose of lyophilisate and type I glass bottle containing 1 ml of solvent, both closed with a butyl elastomer closure and sealed with an aluminium cap.

Pack containing 10 bottles of 1 dose of lyophilisate and 10 bottles of 1 ml of solvent
Pack containing 50 bottles of 1 dose of lyophilisate and 50 bottles of 1 ml of solvent

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

MERIAL
29, avenue Tony Garnier
69007 LYON
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/04/049/001-002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23/02/2005
Date of last renewal: 15/01/2010

10. DATE OF REVISION OF THE TEXT

15/01/2010

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (EMEA) http://www.emea.europa.eu/

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

D. STATEMENT OF THE MRLs

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) of the biological active substance(s)

Merial
Laboratory of Lyon Porte des Alpes
Rue de l'aviation
69800 SAINT-PRIEST
France

Merial
Laboratory of Lyon Gerland
254, Avenue Marcel Mérieux
69007 LYON
France

Name and address of the manufacturer responsible for batch release

Merial
Laboratory of Lyon Porte des Alpes
Rue de l'aviation
69800 SAINT-PRIEST
France

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

To be supplied only on veterinary prescription.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE PRODUCT

Not applicable

D. STATEMENT OF THE MRLs

Not applicable

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Pack of 10 bottles of lyophilisate and 10 bottles of solvent
Pack of 50 bottles of lyophilisate and 50 bottles of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RCCh lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 1ml:
FHV (F2 strain) ..... $\geq 10^{4.9}$ $CCID_{50}$
FCV (431 and G1 strains) ..... ≥ 2.0 ELISA U.
Chlamydophila felis (905 strain) ..... $\geq 10^{3.0}$ EID_{50}
Gentamicin, at most ..... 28 µg

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

Lyophilisate (10 bottles of 1 dose) + solvent (10 bottles of 1 ml)
Lyophilisate (50 bottles of 1 dose) + solvent (50 bottles of 1 ml)

5. TARGET SPECIES

Cats.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP (mm/yyyy)
Use immediately after reconstitution.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MERIAL
29, avenue Tony Garnier
F-69007 LYON
FRANCE

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/04/049/001 Lyophilisate (10 bottles of 1 dose) + solvent (10 bottles of 1 ml)
EU/2/04/049/002 Lyophilisate (50 bottles of 1 dose) + solvent (50 bottles of 1 ml)

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RCCh lyophilisate for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Read the package leaflet before use.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous use

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP (mm/yyyy)

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Solvent bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RCCh solvent

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Read the package leaflet before use.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous use

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP (mm/yyyy)

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Purevax RCCh
Lyophilisate and solvent for suspension for injection.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
MERIAL
29, avenue Tony Garnier
F-69007 Lyon
France

Manufacturer for the batch release:
MERIAL
Laboratoire Porte des Alpes
Rue de l'Aviation
F-69800 Saint Priest
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RCCh
Lyophilisate and solvent for suspension for injection.

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

Per dose of 1ml:

Lyophilisate:
Attenuated feline rhinotracheitis herpesvirus (FHV F2 strain) ..... $\geq 10^{4.9}$ $CCID_{50}$[1]
Inactivated feline Calicivirosis antigens (FCV 431 and FCV G1 strains) ..... ≥ 2.0 ELISA U.
Attenuated *Chlamydophila felis* (905 strain) ..... $\geq 10^{3.0}$ EID_{50}[2]
Excipient:
Gentamicin, at most..... 28 µg

Solvent:
Water for injection .....q.s. 1 ml

[1]: cell culture infective dose 50%
[2]: egg infective dose 50%

4. INDICATION(S)

Active immunisation of cats aged 8 weeks and older:
- against feline viral rhinotracheitis to reduce clinical signs,
- against calicivirus infection to reduce clinical signs and excretion,
- *against Chlamydophila felis* infection to reduce clinical signs.

Onsets of immunity have been demonstrated 1 week after primary vaccination course for rhinotracheitis, calicivirus and *Chlamydophila felis* components.

The duration of immunity is 1 year after the last (re-)vaccination.

5. CONTRAINDICATIONS

Do not use in pregnant animals.
The use is not recommended during lactation

6. ADVERSE REACTIONS

In normal conditions of use, transient apathy and anorexia may occasionally occur, as well as hyperthermia (lasting usually for 1 or 2 days). A local reaction may occur (slight pain at palpation, itching or limited oedema) that disappears within 1 or 2 weeks at most.
In exceptional circumstances a hypersensitivity reaction may occur, which may require appropriate symptomatic treatment.
In very rare cases, hyperthermia and lethargy sometimes associated with lameness has been observed one to three weeks following booster vaccination in adult cats. The reaction was transient
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Inject by subcutaneous route one dose (1ml) of vaccine after reconstitution of the lyophilisate with the solvent, 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 R, C or Ch components are expected to be present (e.g. in kittens of 9-12 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: every year.

9. ADVICE ON CORRECT ADMINISTRATION

Use immediately after reconstitution.
Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administrated with Merial non-adjuvanted vaccine against feline leukaemia and/or administered the same day but not mixed with Merial adjuvanted vaccine against rabies.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store and transport refrigerated (2 °C – 8 °C)
Protect from light.
Do not freeze.

12. SPECIAL WARNING(S)

Use only in healthy animals.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
This vaccine should not be handled by persons who are immunodeficient or taking immunosuppressive medicinal products. If self-injection occurs, immediate medical advice should be sought and the doctor informed that self-injection with a living chlamydial vaccine has occurred.

Do not use in pregnant animals.
The use is not recommended during lactation.

No effect other than those already mentioned in section "Adverse reactions" have been observed after the administration of several doses, except hyperthermia that may exceptionally last 5 days.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15/01/2010

Detailed information on this product is available on the website of the European Medicines Agency (EMEA) http://www.emea.europa.eu/

15. OTHER INFORMATION

Pack containing 10 bottles of 1 dose of lyophilisate and 10 bottles of 1 ml of solvent
Pack containing 50 bottles of 1 dose of lyophilisate and 50 bottles of 1 ml of solvent
Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.