ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax FeLV suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substance
FeLV recombinant Canarypox virus (vCP97) ..... $\geq 10^{7.2}$ CCID50 (cell culture infective dose 50%)

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cats

4.2 Indications for use,specifying the 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.

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

Vaccinate only healthy animals.
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.

4.6 Adverse reactions (frequency and seriousness)

A temporary small (< 2 cm) nodule may appear at the site of injection which regresses within 1 to 4 weeks.
Transient lethargy and hyperthermia may occur for 1 day, exceptionally 2 days.
In exceptional circumstances a hypersensitivity reaction may occur, which may require appropriate symptomatic treatment.

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 administered the same day but not mixed with Merial adjuvanted vaccines (various combinations of feline viral rhinotracheitis, calicivirosis, panleukopenia and rabies components).
Safety and efficacy data are available which demonstrate that this vaccine can be mixed with Merial 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 Merial adjuvanted vaccine against rabies.

4.9 Amounts to be administered and administration route

Subcutaneous use

Administer one dose of 1ml according to the following schedule:

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

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

No undesirable effect has been observed after the administration of several doses except those mentioned in the “Adverse reactions” section.

4.11 Withdrawal period(s)

Not applicable

5. IMMUNOLOGICAL PROPERTIES

ATC vet code: QI06AD

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium chloride
Sodium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Magnesium chloride hexahydrate
Calcium chloride dihydrate
Water for injections.

6.2 Incompatibilities

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Merial non-adjuvanted vaccine range (various combinations of feline viral rhinotracheitis, calicivirosis, panleukopenia and chlamydiosis components)

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Use immediately after broaching.

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

Plastic box containing 10, 20 or 50 type I glass bottle with a Butyl elastomer closure and sealed with an aluminium cap.

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 or by appropriate channels approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

MERIAL
29 avenue Tony Garnier
F-69007 LYON
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/00/019/005-007

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13/04/2000
Date of last renewal: 22/03/2010

10 DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.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 of the biological active substance(s)

MERIAL
Laboratoire Porte des Alpes
Rue de l'Aviation
F-69800 SAINT PRIEST
FRANCE

MERIAL
Laboratoire Lyon Gerland
254, rue Marcel Mérieux
F-69007 Lyon
FRANCE

Name and address of the manufacturer responsible for batch release

MERIAL
Laboratoire Porte des Alpes
Rue de l'Aviation
F-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

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax FeLV suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

FeLV recombinant Canarypox virus (vCP97) ..... $\geq 10^{7.2}$ CCID50

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

10 x 1-ml suspension (10 doses)
20 x 1-ml suspension (20 doses)
50 x 1-ml suspension (50 doses)

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/yy)
Use immediately after broaching

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/2/00/019/005 10 doses: 1-ml suspension (10 bottles)
EU/2/00/019/006 20 doses: 1-ml suspension (20 bottles)
EU/2/00/019/007 50 doses: 1-ml suspension (50 bottles)

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax FeLV suspension 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

Not applicable

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Purevax FeLV
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

Manufacturing authorisation holder responsible for batch release
MERIAL
Laboratoire Porte des Alpes
Rue de l'Aviation
F-69800 SAINT PRIEST
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax FeLV
Suspension for injection

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

Each dose of 1ml contains:

FeLV recombinant Canarypox virus (vCP97) ..... $\geq 10^{7.2}$ CCID50 (cell culture infective dose 50%)

4. INDICATION(S)

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

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

6. ADVERSE REACTIONS

A temporary small (< 2 cm) nodule may appear at the site of injection which regresses within 1 to 4 weeks
Transient lethargy and hyperthermia may occur for 1 day, exceptionally 2 days.

In exceptional circumstances a hypersensitivity reaction may occur, which may require appropriate symptomatic treatment.
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

Subcutaneous use
Administer one dose of 1ml - 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.
Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Merial non-adjuvanted vaccine range (various combinations of feline viral rhinotracheitis, calicivirosis, panleukopenia and chlamydiosis components)

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.
Use immediately after broaching.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Safety and efficacy data are available which demonstrate that this vaccine can be administered the same day but not mixed with Merial adjuvanted vaccines (various combinations of feline viral rhinotracheitis, calicivirosis, panleukopenia and rabies components).

Safety and efficacy data are available which demonstrate that this vaccine can be mixed with Merial 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 Merial adjuvanted vaccine against rabies.

No undesirable effect has been observed after the administration of several doses except those mentioned in the "Adverse reactions" section.

Do not mix with any other vaccine or immunological product except Merial non-adjuvanted vaccine range.

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 or by appropriate channels approved for use by the competent authorities.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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

15. 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.

Plastic box containing 10, 20 or 50 bottles
Not all pack sizes may be marketed.