

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 %

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

Light pink to pale yellow homogeneous suspension

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the 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.

4.3 Contraindications

None.

4.4 Special warnings

None.

4.5 Special precautions for use

Special precautions for use in animals

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 transiently.

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)

In very rare cases, transient and slight apathy may occur, as well as mild anorexia or hyperthermia (above 39.5 °C), usually lasting 1 or 2 days. Most of these reactions were noted during the 2 days following the vaccine injection.

A transient local reaction may very rarely occur (pain at palpation, limited swelling that may become nodular, heat at the injection site, and in some cases erythema), that usually disappears within 1 or 2 weeks at most.

Very rarely, a hypersensitivity reaction may occur, which may require appropriate symptomatic treatment.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

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

4.8 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 Merial non-adjuvanted vaccine against feline leukaemia.

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

4.9 Amounts to be administered and administration route

Subcutaneous use.

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.

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

No adverse reactions other than those already mentioned in section 4.6 have been observed after the administration of 10 doses. The reactions may last longer.

4.11 Withdrawal period

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other immunologicals for cats.
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.

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

Do not mix with any other veterinary medicinal product, except those mentioned in section 4.8.

6.3 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.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Type I glass vial with a butyl elastomer closure, sealed with an aluminium cap.

Box of 2 or 10 or 50 vials of 1 dose.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with the local requirements.

7. MARKETING AUTHORISATION HOLDER

MERIAL
29 avenue Tony Garnier
69007 LYON
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/117/001
EU/2/10/117/002
EU/2/10/117/003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18/02/2011
Date of last renewal:

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. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers of the biological active substance

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

MERIAL
Laboratoire Lyon Gerland
254, rue Marcel Mérieux
69007 LYON
FRANCE

Name and address of the manufacturer responsible for batch release

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 10 vials of suspension for injection
Box of 50 vials of suspension for injection
Box of 2 vials of suspension for injection

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax Rabies suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:

Rabies recombinant canarypox virus (vCP65) $\geq 10^{6.8}$ FAID₅₀

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

10 x 1 ml

50 x 1 ml

2 x 1 ml

5. TARGET SPECIES

Cats.

6. INDICATION

7. METHOD AND ROUTE OF ADMINISTRATION

Subcutaneous use.

Read the package leaflet before use

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP (month/year)
Once broached, use immediately.

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

Disposal: Read package leaflet.

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 SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MERIAL
29, avenue Tony Garnier
69007 Lyon
FRANCE

16. MARKETING AUTHORISATION NUMBER(S)

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

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax Rabies

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

1 dose

4. ROUTE OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP (month/year)

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Purevax Rabies 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
69007 Lyon
FRANCE

Manufacturer responsible for batch release:

MERIAL
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint Priest
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax Rabies suspension for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

Each dose of 1 ml contains:

Rabies recombinant canarypox virus (vCP65) $\geq 10^{6.8}$ FAID*₅₀

*Fluorescent assay infectious dose 50 %

Light pink to pale yellow homogeneous suspension

4. INDICATION

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. ADVERSE REACTIONS

In very rare cases, transient and slight apathy may occur, as well as mild anorexia or hyperthermia (above 39.5 °C), usually lasting 1 or 2 days. Most of these reactions were noted during the 2 days following the vaccine injection

A transient local reaction may very rarely occur (pain at palpation, limited swelling that may become nodular, heat at the injection site, and in some cases erythema), that usually disappears within 1 or 2 weeks at most.

Very rarely, a hypersensitivity reaction may occur, which may require appropriate symptomatic treatment.

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- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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 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 PERIOD

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 container: use immediately.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

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 Merial non-adjuvanted vaccine against feline leukaemia.

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

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

Overdose:

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with the local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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

15. 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.

Box of 10 vials of 1 dose.

Box of 50 vials of 1 dose.

Box of 2 vials of 1 dose.

Not all pack sizes may be marketed.