

**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:

### Lyophilisate:

#### **Active substances:**

Attenuated feline rhinotracheitis herpesvirus (FHV F2 strain) .....  $\geq 10^{4.9}$  CCID<sub>50</sub><sup>1</sup>

Inactivated feline calicivirus (FCV 431 and G1 strains) antigens .....  $\geq 2.0$  ELISA U.

#### **Excipient:**

Gentamicin, at most..... 16.5 µg

### Solvent:

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

<sup>1</sup> cell culture infective dose 50%

For the 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, specifying the 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.

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

The duration of immunity after the last re-vaccination is 3 years for the rhinotracheitis and calicivirosis components.

### 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 in 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.

#### **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.

#### **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 rhinotracheitis or calicivirosis 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:

- the first revaccination must be carried out one year after the primary vaccination course,
- subsequent revaccinations must be carried out at intervals of up to three years for the rhinotracheitis and calicivirosis components.

#### **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**

ATCvet code: QI06AH08.

Vaccine against feline viral rhinotracheitis and feline calicivirosis.

Stimulates active immunity against feline rhinotracheitis herpesvirus and feline calicivirus.

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

### **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**

Do not mix with Merial adjuvanted vaccine against rabies.

#### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

Shelf life after reconstitution according to directions: use immediately.

#### **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 or plastic 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**

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

**7. MARKETING AUTHORISATION HOLDER**

MERIAL  
29, avenue Tony Garnier  
69007 LYON  
FRANCE

**8. MARKETING AUTHORISATION NUMBER(S)**

EU/2/04/051/001-002

**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**

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 SUBSTANCES AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**

**A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturers of the biological active substances

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 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**

**Pack containing 10 bottles of lyophilisate and 10 bottles of solvent**  
**Pack 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 AND OTHER SUBSTANCES**

Per dose of 1 ml:

FHV (F2 strain) .....  $\geq 10^{4.9}$  CCID<sub>50</sub>

FCV (431 and G1 strains) .....  $\geq 2.0$  ELISA U.

**3. PHARMACEUTICAL FORM**

Lyophilisate and solvent for suspension for injection.

**4. PACKAGE SIZE**

Lyophilisate (10x1 dose) + solvent (10x1 ml)

Lyophilisate (50x1 dose) + solvent (50x1 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)

Once reconstituted use immediately.

**11. SPECIAL STORAGE CONDITIONS**

Store and transport refrigerated.

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/2/04/051/001 Lyophilisate (10 bottles of 1 dose) + solvent (10 bottles of 1 ml)

EU/2/04/051/002 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 RC

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

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

1 dose

**4. ROUTE(S) OF ADMINISTRATION**

SC

**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 RC solvent

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

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

1 dose

**4. ROUTE(S) OF ADMINISTRATION**

SC

**5. WITHDRAWAL PERIOD**

**6. BATCH NUMBER**

Lot

**7. EXPIRY DATE**

EXP (mm/yyyy)

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET FOR:

### Purevax RC 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  
69007 Lyon  
FRANCE

Manufacturing authorisation holder 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 RC lyophilisate and solvent for suspension for injection.

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

Per dose of 1 ml:

**Lyophilisate:**

Attenuated feline rhinotracheitis herpesvirus (FHV F2 strain) .....  $\geq 10^{4.9}$  CCID<sub>50</sub><sup>1</sup>  
Inactivated feline calicivirus (FCV 431 and FCV G1 strains) antigens .....  $\geq 2.0$  ELISA U.

**Excipient:**

Gentamicin, at most..... 16.5 µg

**Solvent:**

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

<sup>1</sup> cell culture 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.

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

The duration of immunity after the last re-vaccination is 3 years for the rhinotracheitis and calicivirosis components.

## **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.

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 (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 rhinotracheitis or calicivirosis 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:

- the first revaccination must be carried out one year after the primary vaccination course,
- subsequent revaccinations must be carried out at intervals of up to three years for the rhinotracheitis and calicivirosis components.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Use immediately after reconstitution.

## **10. WITHDRAWAL PERIOD(s)**

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.

## **12. SPECIAL WARNING(S)**

### Special precautions for use in animals:

Use in 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 in pregnant animals.

The use is not recommended during 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 Merial non-adjuvanted vaccine against feline leukaemia and/or administered the same day but not mixed with Merial adjuvanted vaccine against rabies.

### Overdose (symptoms, emergency procedures, antidotes):

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.

### Incompatibilities:

Do not mix with Merial adjuvanted vaccine against rabies.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

## **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**

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.

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

To be supplied only on veterinary prescription.