

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RCPCh lyophilisate and solvent for suspension for injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 1 ml or 0.5 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.  
Attenuated *Chlamydomydia felis* (905 strain) .....  $\geq 10^{3.0}$  EID<sub>50</sub><sup>2</sup>  
Attenuated feline panleucopenia virus (PLI IV) .....  $\geq 10^{3.5}$  CCID<sub>50</sub><sup>1</sup>

#### **Excipient:**

Gentamicin, at most ..... 28 µg

### Solvent:

Water for injections ..... q.s. 1 ml or 0.5 ml.

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

<sup>2</sup> egg infective dose 50%

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

Lyophilisate: homogeneous beige pellet.

Solvent: clear colourless liquid.

## 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,
- against *Chlamydomydia felis* infection to reduce clinical signs,
- against feline panleucopenia to prevent mortality and clinical signs.

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

Duration of immunity:

- Rhinotracheitis, calicivirosis and panleucopenia components: 1 year after primary vaccination course and 3 years after the last re-vaccination
- *Chlamydomydia felis* component: 1 year after the last re-vaccination.

### **4.3 Contraindications**

None.

### **4.4 Special warnings for each target species**

Vaccinate healthy animals only.

### **4.5 Special precautions for use**

#### Special precautions for use in animals

None.

#### 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)**

Transient apathy and anorexia as well as hyperthermia (lasting usually for 1 or 2 days) were commonly observed during safety and field studies. A local reaction (slight pain at palpation, itching or limited oedema) that disappears within 1 or 2 weeks at most was commonly observed during safety and field studies.

A hypersensitivity reaction has been observed uncommonly in field studies, which may require appropriate symptomatic treatment.

Emesis (mostly within 24 to 48 hours) has been observed in very rare cases based on post-marketing safety experience.

Transient hyperthermia and lethargy, sometimes associated with lameness, have been observed 1 to 3 weeks booster vaccination in adult cats, in very rare cases, based on post marketing safety experience.

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

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

### **4.7 Use during pregnancy, lactation or lay**

Do not use during the whole pregnancy and 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 and administered with Boehringer Ingelheim non-adjuvanted vaccine against feline leukaemia and/or administered the same day but not mixed with Boehringer Ingelheim adjuvanted vaccine against rabies.

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Boehringer Ingelheim non-adjuvanted vaccine against rabies.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

#### **4.9 Amounts to be administered and administration route**

Subcutaneous route.

Reconstitute gently the vaccine in order to obtain a uniform suspension with limited foam formation. Visual appearance after reconstitution: clear slightly yellow suspension.

After reconstitution of the lyophilisate with 0.5 ml or 1 ml of the solvent (depending on the presentation chosen), inject one dose of vaccine 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, calicivirosis, panleucopenia or *Chlamydophila* components are expected to be present (e.g. in kittens of 9 to 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:

- the first revaccination must be carried out for all components one year after the primary vaccination course,
- subsequent revaccinations must be carried out
  - Chlamydiosis component: every year.
  - Rhinotracheitis, calicivirosis and panleucopenia components: at intervals of up to three years.

#### **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: QI06AJ03. live feline rhinotracheitis virus + inactivated feline calicivirus antigen + live feline panleucopenia virus / parvovirus + live chlamydia.

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

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 Major incompatibilities**

Do not mix with Boehringer Ingelheim 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 or 0.5 ml of solvent, both closed with a butyl elastomer closure and sealed with an aluminium or plastic cap.

Plastic box containing 10 bottles of 1 dose of lyophilisate and 10 bottles of 1 ml of solvent.  
Plastic box containing 50 bottles of 1 dose of lyophilisate and 50 bottles of 1 ml of solvent.  
Plastic box containing 10 bottles of 1 dose of lyophilisate and 10 bottles of 0.5 ml of solvent.  
Plastic box containing 50 bottles of 1 dose of lyophilisate and 50 bottles of 0.5 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**

Boehringer Ingelheim Vetmedica GmbH  
55216 Ingelheim/Rhein  
GERMANY

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

EU/2/04/050/001-004

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 23/02/2005

Date of last renewal: 14/01/2010

**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.