

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Plastic box of 10 bottles of lyophilisate and 10 bottles of solvent; Plastic box of 50 bottles of lyophilisate and 50 bottles of solvent)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Purevax RCPCh lyophilisate and solvent for suspension for injection.

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Per dose of 1 ml or 0.5 ml:

FHV (F2 strain) .....	$\geq 10^{4.9}$ CCID <sub>50</sub>
FCV (431 and G1 strains).....	$\geq 2.0$ ELISA U.
<i>Chlamydophila felis</i> (905 strain) .....	$\geq 10^{3.0}$ EID <sub>50</sub>
FPV (PLI IV).....	$\geq 10^{3.5}$ CCID <sub>50</sub> .

**3. PACKAGE SIZE**

Lyophilisate (10 x 1 dose) + solvent (10 x 1 ml)  
Lyophilisate (50 x 1 dose) + solvent (50 x 1 ml)  
Lyophilisate (10 x 1 dose) + solvent (10 x 0.5 ml)  
Lyophilisate (50 x 1 dose) + solvent (50 x 0.5 ml)

**4. TARGET SPECIES**

Cats

**5. INDICATION(S)**

**6. ROUTES OF ADMINISTRATION**

Subcutaneous use.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. (dd/mm/yyyy)  
Once reconstituted use immediately.

**9. SPECIAL STORAGE PRECAUTIONS**

Store and transport refrigerated.  
Protect from light.  
Do not freeze.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children

**13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Boehringer Ingelheim Vetmedica GmbH

**14. MARKETING AUTHORISATION NUMBERS**

Vm 04491/5055

**15. BATCH NUMBER**

Lot

**16. SPECIAL WARNING(S), IF NECESSARY**

**17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

**18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]**

POM-V To be supplied only on veterinary prescription
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**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS (LYOPHILISATE BOTTLE)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Purevax RCPCh



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)**

1 dose

**3. BATCH NUMBER**

Lot

**4. EXPIRY DATE**

Exp. (dd/mm/yyyy)

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

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

**7. WITHDRAWAL PERIOD**

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS (SOLVENT BOTTLE)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Purevax RCPCh solvent



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)**

1 ml or 0.5 ml

**3. BATCH NUMBER**

Lot

**4. EXPIRY DATE**

Exp. (mm/yyyy)

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

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

**7. WITHDRAWAL PERIOD**

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

## **PACKAGE LEAFLET:**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Purevax RCPCh lyophilisate and solvent for suspension for injection.

### **2. COMPOSITION**

Per dose of 1 ml or 0.5 ml:

#### **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 FCV G1 strains) antigens	$\geq 2.0$ ELISA U.
Attenuated <i>Chlamydomphila felis</i> (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>

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

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

#### Solvent:

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

Lyophilisate: homogeneous beige pellet.

Solvent: clear colourless liquid.

### **3. TARGET SPECIES**

Cats

### **4. 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,
- against *Chlamydomphila 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, *Chlamydomphila felis* and panleucopenia components.

Duration of immunity:

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

### **5. CONTRAINDICATIONS**

None.

## 6. SPECIAL WARNING(S)

Vaccinate 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.

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.

### Pregnancy and lactation:

Do not use during the whole pregnancy and lactation.

### Interactions 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.

### Overdose:

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

### Special restrictions for use and special conditions for use:

For administration only by a veterinarian.

### Major incompatibilities:

Do not mix with Boehringer Ingelheim adjuvanted vaccine against rabies.

## 7. ADVERSE EVENTS

Cats:

<b>Common</b> (1 to 10 animals / 100 animals treated):
Transient apathy, anorexia, and hyperthermia <sup>1</sup> (observed during safety and field studies).
Injection site reactions (slight pain at palpation, itching or limited oedema) <sup>2</sup> (observed during safety and field studies)

<b>Uncommon</b> (1 to 10 animals / 1,000 animals treated):
Hypersensitivity reaction <sup>3</sup> (observed in field studies)
<b>Very rare</b> (<1 animal / 10,000 animals treated, including isolated reports):
Emesis <sup>4</sup> , transient hyperthermia and lethargy, sometimes associated with lameness <sup>5</sup> (based on post-marketing experience)

<sup>1</sup> lasting usually for 1 or 2 days

<sup>2</sup> disappearing within 1 or 2 weeks at most

<sup>3</sup> may require appropriate symptomatic treatment.

<sup>4</sup> mostly within 24 to 48 hours

<sup>5</sup> observed 1 to 3 weeks following booster vaccination in adult cats

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

Subcutaneous route.

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, calicivirolosis, 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, calicivirolosis and panleucopenia components: at intervals of up to three years.

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

Reconstitute gently the vaccine in order to obtain a uniform suspension with limited foam formation.

Visual appearance after reconstitution: clear slightly yellow suspension.

## **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.

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle after EXP.

Shelf life after reconstitution according to directions: use immediately.

## **12. SPECIAL PRECAUTIONS FOR DISPOSAL**

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

## **13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

## **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

Vm 04491/5055

Plastic box containing:

10 x 1 dose of lyophilisate and 10 x 1 ml of solvent or

50 x 1 dose of lyophilisate and 50 x 1 ml of solvent or

10 x 1 dose of lyophilisate and 10 x 0.5 ml of solvent or

50 x 1 dose of lyophilisate and 50 x 0.5 ml of solvent.

Not all pack sizes may be marketed.

## **15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED**

March 2023



## 16. CONTACT DETAILS

### Marketing authorisation holder:

Boehringer Ingelheim Vetmedica GmbH  
55216 Ingelheim/Rhein  
Germany

### Manufacturer responsible for batch release:

Boehringer Ingelheim Animal Health France SCS  
Laboratoire Porte des Alpes  
Rue de l'Aviation  
69800 Saint Priest  
France

Local representatives and contact details to report suspected adverse reactions

### **België/Belgique/Belgien**

Boehringer Ingelheim Animal  
Health Belgium SA  
Tél/Tel: + 32 2 773 34 56

### **Република България**

Boehringer Ingelheim RCV GmbH & Co KG  
Tel: +359 2 958 79 98

### **Česká republika**

Boehringer Ingelheim spol. s r.o.  
Tel: +420 234 655 111

### **Danmark**

Boehringer Ingelheim Animal Health Nordics  
A/S  
Tlf: + 45 3915 8888

### **Deutschland**

Boehringer Ingelheim Vetmedica GmbH  
Tel: 0800 290 0 270

### **Eesti**

Boehringer Ingelheim RCV GmbH & Co KG  
Eesti filiaal  
Tel: +372 612 8000

### **Ελλάδα**

Boehringer Ingelheim Vetmedica GmbH  
Τηλ: +30 2108906300

### **España**

Boehringer Ingelheim Animal Health España,  
S.A.U.

### **Lietuva**

Boehringer Ingelheim RCV GmbH & Co  
KG  
Lietuvos filialas  
Tel: +370 5 2595942

### **Luxembourg/Luxemburg**

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Health Belgium SA  
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### **Magyarország**

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& CoKG  
Magyarországi Fióktelep  
Tel: +36 1 299 8900

### **Malta**

Boehringer Ingelheim Animal Health UK  
Limited  
Tel: +44 1344 746957

### **Nederland**

Boehringer Ingelheim Animal Health  
Netherlands bv  
Tel: +31 20 799 6950

### **Norge**

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### **Österreich**

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### **Polska**

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**Κύπρος**

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Latvijas filiāle

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**Portugal**

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ugal, Unipessoal, Lda.

Tel: +351 21 313 5300

**România**

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KG

Viena - Sucursala București

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**Slovenija**

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KG

Podružnica Ljubljana

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**Slovenská republika**

Boehringer Ingelheim RCV GmbH & Co  
KG, o.z.

Tel: +421 2 5810 1211

**Suomi/Finland**

Vetcare Oy

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**Sverige**

Boehringer Ingelheim Animal Health  
Nordics A/S

Tlf: +46 (0)40-23 34 00

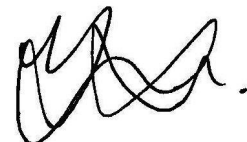
**United Kingdom**

Boehringer Ingelheim Animal Health UK  
Limited

Tel: + 44 1344 746957

**17. OTHER INFORMATION**

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



Approved: 30 March 2023