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) ..... $\geq 10^{4.9}$ $CCID_{50}$
FCV (431 and G1 strains)..... ≥ 2.0 ELISA U.
Chlamydophila felis (905 strain) ..... $\geq 10^{3.0}$ EID_{50}
FPV (PLI IV)..... $\geq 10^{3.5}$ $CCID_{50}$.

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 61700/5072

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

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)	$\geq 10^{4.9}$ $CCID_{50}$[1]
Inactivated feline calicivirus (FCV 431 and FCV G1 strains) antigens	≥ 2.0 ELISA U.
Attenuated *Chlamydophila felis* (905 strain)	$\geq 10^{3.0}$ EID_{50}[2]
Attenuated feline panleucopenia virus (PLI IV)	$\geq 10^{3.5}$ $CCID_{50}$[1]

[1] cell culture infective dose 50%
[2] 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 Chlamydophila 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, *Chlamydophila 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
- *Chlamydophila 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:

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

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

[1] lasting usually for 1 or 2 days
[2] disappearing within 1 or 2 weeks at most
[3] may require appropriate symptomatic treatment.
[4] mostly within 24 to 48 hours
[5] 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, 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.

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 61700/5072

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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am 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
Boehringer Ingelheim Animal Health Belgium SA
Tél/Tel: + 32 2 773 34 56

Magyarország
Boehringer Ingelheim RCV GmbH & 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
Boehringer Ingelheim Animal Health Nordics A/S
Tlf: +47 66 85 05 70

Österreich
Boehringer Ingelheim RCV GmbH & Co KG
Tel: +43 1 80105-6880

Polska
Boehringer Ingelheim Sp. z o.o.
Tel.: + 48 22 699 0 699

Tel: +34 93 404 51 00

France
Boehringer Ingelheim Animal Health France, SCS
Tél: +33 4 72 72 30 00

Hrvatska
Boehringer Ingelheim RCV GmbH & Co KG
Tel: +385 1 2444 600

Ireland
Boehringer Ingelheim Animal Health UK Limited
Tel: +353 1 291 3985

Ísland
Vistor hf.
Sími: + 354 535 7000

Italia
Boehringer Ingelheim Animal Health Italia S.p.A.
Tel: +39 02 53551

Κύπρος
Boehringer Ingelheim Vetmedica GmbH
Τηλ: +30 2108906300

Latvija
Boehringer Ingelheim RCV GmbH & Co KG
Latvijas filiāle
Tel: +371 67 240 011

Portugal
Boehringer Ingelheim Animal Health Portugal, Unipessoal, Lda.
Tel: +351 21 313 5300

România
Boehringer Ingelheim RCV GmbH & Co KG
Viena - Sucursala Bucureşti
Tel: +40 21 302 28 00

Slovenija
Boehringer Ingelheim RCV GmbH & Co KG
Podružnica Ljubljana
Tel: +386 1 586 40 00

Slovenská republika
Boehringer Ingelheim RCV GmbH & Co KG, o.z.
Tel: +421 2 5810 1211

Suomi/Finland
Vetcare Oy
Puh/Tel: + 358 201443360

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