PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Plastic box containing 10 bottles of lyophilisate and 10 bottles of solvent
Plastic box 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 or 0.5 ml:

FHV (F2 strain)	$\geq 10^{4.9}$ $CCID_{50}$
FCV (431 and G1 strains)	$\geq$ 2.0 ELISA U.

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
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

14. MARKETING AUTHORISATION NUMBER

Vm 04491/5052

15. BATCH NUMBER

Lot {number}

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

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RC 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

1 dose
1 ml or 0.5 ml

3. BATCH NUMBER

Lot {number}

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 RC solvent 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

1 ml or 0.5 ml

3. BATCH NUMBER

Lot {number}

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”

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RC lyophilisate and solvent for suspension for injection

2. COMPOSITION

Per dose of 1 ml or 0.5 ml:

Active substances:
Lyophilisate:
Attenuated feline rhinotracheitis herpesvirus (FHV F2 strain) $\geq 10^{4.9}$ $CCID_{50}$[1]
Inactivated feline calicivirus (FCV 431 and FCV G1 strains) antigens $\geq$ 2.0 ELISA U.

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

[1] cell culture infective dose 50%.

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.

Onset of immunity: 1 week after primary vaccination course.
Duration of immunity: 1 year after primary vaccination course and 3 years 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.

Pregnancy and lactation:
Do not use during the whole pregnancy and 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 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 adverse event other than those already mentioned in section “Adverse events” have been observed, except hyperthermia that may exceptionally last 5 days.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the veterinary medicinal product and except those mentioned in section “Interaction with other medicinal products and other forms of interaction” above.

7. ADVERSE EVENTS

Cats:

- Common (1 to 10 animals / 100 animals treated): Apathy, anorexia, and hyperthermia[1]. Injection site reactions (pain, itching, oedema)[2]

- Uncommon (1 to 10 animals / 1 000 animals treated): Hypersensitivity reaction[3]

- Very rare (<1 animal / 10 000 animals treated, including isolated reports): Emesis[4]

[1] lasting usually for 1 or 2 days.
[2] slight pain at palpation, itching or limited oedema disappearing within 1 or 2 weeks at most.
[3] which may require appropriate symptomatic treatment.
[4] mostly within 24 to 48 hours.

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 marketing authorisation holder or 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 or calicivirosis 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 one year after the primary vaccination course,
- subsequent revaccinations: 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 ^{o}C – 8 ^{o}C)
Protect from light.
Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after Exp.
Shelf life after reconstitution according to directions: use immediately.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

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.

Vm 04491/5052

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

July 2023

16. CONTACT DETAILS

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

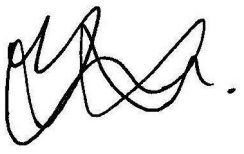
Manufacturing authorisation holder responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint-Priest
France

Local representatives and contact details to report suspected adverse reactions:

United Kingdom
Boehringer Ingelheim Animal Health UK Limited
Bracknell, RG12 8YS
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: 07 July 2023