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 FeLV 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) ..... $\geq 10^{3.5}$ $CCID_{50}$
FeLV recombinant canarypox virus (vCP97)..... $\geq 10^{7.2}$ $CCID_{50}$.

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 04491/5056

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 FeLV

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 FeLV solvent

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

1 ml or 0.5 ml

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”

PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RCPCh FeLV 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 .. ≥ 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]

Solvent:
FeLV recombinant canarypox virus (vcp97) ..... $\geq 10^{7.2}$ $CCID_{50}$[1]

[1] cell culture infective dose 50%.
[2] egg infective dose 50%.

Lyophilisate: homogeneous beige pellet.
Solvent: clear colourless liquid with presence of cell debris in suspension.

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 C*hlamydophila felis* infection to reduce clinical signs,
- Against feline panleucopenia to prevent mortality and clinical signs,
- Against leukaemia to prevent persistent viraemia and clinical signs of the related disease.

Onsets of immunity: Rhinotracheitis, calicivirus, *Chlamydophila felis* and panleucopenia components: 1 week after primary vaccination course.
Feline leukaemia component: 2 weeks after primary vaccination course.

Duration of immunity:
- Rhinotracheitis, calicivirosis and panleucopenia components:1 year after primary vaccination course and 3 years after the last re-vaccination.
- *Chlamydophila felis* and feline leukaemia components: 1 year after the last re-vaccination.
-

5. CONTRAINDICATIONS

None

6. SPECIAL WARNING(S)

Vaccinate healthy animals only.

Special precautions for safe use in the target species:
It is recommended that a test for felv antigenaemia be carried out prior to vaccination. Vaccination of felv positive cats is of no benefit.

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 insert 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 administered the same day but not mixed with Boehringer Ingelheim 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, 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 any other veterinary medicinal product, except the solvent supplied for use with the product.

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:
    - Chlamydiosis and feline leukaemia components: 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: slightly yellow suspension with presence of cell debris in 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 label 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 04491/5056

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.

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:

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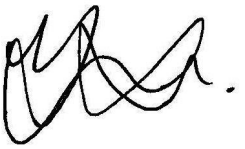
17. OTHER INFORMATION

The feline leukaemia vaccine strain is a recombinant canarypox virus expressing the *env* and *gag* genes of FeLV-A. Under field conditions, only sub-group A is infective and immunisation against sub-group A provides full protection against A, B and C. After inoculation, the virus expresses the protective proteins, but does not replicate in the cat. As a consequence, the vaccine induces an immune status against feline leukaemia virus.

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



Approved: 28 March 2023