SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Solvent:
Active substance:
FeLV recombinant canarypox virus (vCP97) .....≥ $10^{7.2}$ $CCID_{50}$[1]

[1] cell culture infective dose 50%
[2] 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 with presence of cell debris in suspension.

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 *Chlamydophila 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.

Onset 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.

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
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 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)

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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

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 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.

4.9 Amount(s) 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: slightly yellow suspension with presence of cell debris in 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:
    - Chlamydiosis and feline leukaemia components: 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: QI06AJ05. live feline rhinotracheitis virus + inactivated feline calicivirus antigen + live feline panleucopenia virus / parvovirus + live chlamydia + feline leukaemia recombinant live canarypox virus

Vaccine against feline viral rhinotracheitis, feline calicivirosis, chlamydiosis, feline panleucopenia and feline leukaemia.
Stimulates active immunity against feline rhinotracheitis herpesvirus, feline calicivirus, *Chlamydophila felis*, feline panleucopenia virus and feline leukaemia virus.
The product was shown to reduce excretion of feline calicivirus at onset of immunity and for one year after vaccination.
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.

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
Potassium chloride
Disodium phosphate dihydrate
Magnesium chloride hexahydrate
Calcium chloride dihydrate

6.2 Major Incompatibilities

Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the product.

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 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
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8. MARKETING AUTHORISATION NUMBER

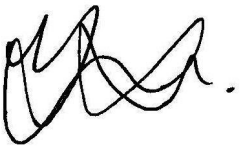
Vm 04491/5056

9. DATE OF FIRST AUTHORISATION

22 February 2005

10. DATE OF REVISION OF THE TEXT

March 2023



Approved: 28 March 2023