SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax RC lyophilisate and solvent for suspension for injection

2. QUALITATIVE AND QUANTITATIVE 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 G1 strains) antigens	$\geq$ 2.0 ELISA U.

[1] cell culture 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.

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.

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.

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
None.

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.

4.6 Adverse reactions (frequency and seriousness)

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 may require appropriate symptomatic treatment.
4 mostly within 24 to 48 hours.

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 section “Contact details” of the package leaflet.

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 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.

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: clear slightly yellow 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 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse event 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: QI06AH08. Live feline rhinotracheitis virus + inactivated feline calicivirus antigen.

Vaccine against feline viral rhinotracheitis and feline calicivirosis.
Stimulates active immunity against feline rhinotracheitis herpesvirus and feline calicivirus.

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

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
Water for injections

6.2 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 4.8 above.

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 or plastic 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 61700/5068

9. DATE OF FIRST AUTHORISATION

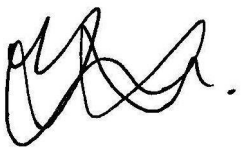
23 February 2005

10. DATE OF REVISION OF THE TEXT

July 2023

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription



Approved: 07 July 2023