SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax FeLV suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of I ml or 0.5 ml:

Active substances:
FeLV recombinant Canaryypox virus (vCP97) $\geq 10^{7.2}$ $CCID_{50}$[1]

[1]cell culture infective dose 50%

Excipients:

Qualitative composition of excipients and other constituents
Potassium chloride
Sodium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Magnesium chloride hexahydrate
Calcium chloride dihydrate
Water for injections

Clear colourless liquid with presence of cell debris in suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

Active immunisation of cats of 8 weeks of age or older against feline leukaemia for the prevention of persistent viraemia and clinical signs of the related disease.

Onset of immunity: 2 weeks after primary vaccination course.
Duration of immunity: 1 year after the last vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

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 leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cats:

Very common (>1 animal / 10 animals treated):	Injection site nodule.[1] Lethargy, hyperthermia.[2]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anorexia, emesis. Hypersensitivity reaction, anaphylaxis.[3]

[1]Small (< 2 cm) , regresses within 1 to 4 weeks.
[2]Lasting usually for 1 day, exceptionally for 2 days.
[3]If such reactions occur, appropriate treatment is recommended.
May evolve to a more severe condition (anaphylaxis). If such reactions occur, appropriate treatment is recommended.

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Do not use during the whole pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be mixed with Boehringer Ingelheim non-adjuvanted vaccine range (various combinations of feline viral rhinotracheitis, calicivirosis, panleukopenia and chlamydiosis

components) and/or 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.

3.9 Administration routes and dosage

Subcutaneous use.

Administer one dose of 1 ml or 0.5 ml (depending on the presentation chosen) according to the following schedule:

Basic vaccination: first injection: from 8 weeks of age,
second injection: 3 to 5 weeks later.
Revaccination: annual

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse events other than those already mentioned in section 3.6 “Adverse events” have been observed.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI06AD07

The 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medical product, except those mentioned in section 3.8 above.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Protect from light.
Do not freeze.

5.4 Nature and composition of immediate packaging

Type I glass bottle containing 1 ml or 0.5 ml of vaccine, closed with a butyl elastomer closure and sealed with an aluminium cap.

Plastic box containing 10, 20 or 50 bottles of 1 ml of vaccine.
Plastic box containing 10, 20 or 50 bottles of 0.5 ml of vaccine.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 61700/5066

8. DATE OF FIRST AUTHORISATION

13 April 2000

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

January 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Approved 03 June 2025

Gavin Hall