SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax FeLV suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml or 0.5 ml contains:

Active substance:
FeLV recombinant Canarypox virus (vCP97).....≥ $10^{7.2}$ $CCID50^{1}$
[1] cell culture infective dose 50%

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
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 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.

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.

4.6 Adverse reactions (frequency and seriousness)

A temporary small (< 2 cm) nodule, which regresses within 1 to 4 weeks, was very commonly observed at the site of injection during safety and field studies.
Transient lethargy and hyperthermia were very commonly observed during safety and field studies and lasted usually for 1 day, exceptionally for 2 days.
Anorexia and emesis have been reported very rarely based on post marketing safety experience.
A hypersensitivity reaction may occur in very rare cases. Such reactions may evolve to a more severe condition (anaphylaxis). If such reactions occur, appropriate treatment is recommended.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals treated in 100 animals)
- uncommon (more than 1 but less than 10 animals treated in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 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.

4.9 Amounts to be administered and administration route

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

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

No other effect has been observed except those mentioned in section 4.6 “Adverse reactions”.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

ATC vet code: QI06AD07 Live viral vaccines, feline leukaemia, recombinant live canarypox virus.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium chloride
Sodium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Magnesium chloride hexahydrate
Calcium chloride dihydrate
Water for injections.

6.2 Major incompatibilities

Do not mix with any other vaccine or immunological product except Boehringer Ingelheim non- adjuvanted vaccine range (various combinations of feline viral rhinotracheitis, calicivirosis, panleukopenia and chlamydiosis components).

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
2 years. Shelf life after broaching: 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 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.

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 04491/5050

9. DATE OF FIRST AUTHORISATION

13 April 2000

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

Approved 01 April 2022