ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Plastic box of 10 bottles of vaccine Plastic box of 20 bottles of vaccine Plastic box of 50 bottles of vaccine

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax FeLV suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 1 ml or 0.5 ml:
FeLV recombinant Canarypox virus (vCP97) ≥ $10^{7.2}$ CCID50

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

10 x 1 ml (10 doses)
20 x 1 ml (20 doses)
50 x 1 ml (50 doses)
10 x 0.5 ml (10 doses)
20 x 0.5 ml (20 doses)
50 x 0.5 ml (50 doses)

5. TARGET SPECIES

Cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP (mm/yy)
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Protect from light.
Do not freeze.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE,

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 04491/5050

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax FeLV

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

0.5 ml or 1 ml

4. ROUTE(S) OF ADMINISTRATION

SC.

5. WITHDRAWAL PERIOD(S)

Not applicable

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Purevax FeLV suspension for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

Manufacturing authorisation holder responsible for batch release
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 SAINT PRIEST
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax FeLV suspension for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose of 1 ml or 0.5ml contains:

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

Clear colourless liquid with presence of cell debris in suspension.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Subcutaneous use.

Administer one dose of 1ml or 0.5 ml of vaccine (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

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

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.
Shelf life after broaching: use immediately.
Do not use this veterinary medicinal product after the expiry date, which is stated on the label after EXP.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

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.

Pregnancy and lactation:
Do not use during the whole pregnancy and lactation.

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.

Overdose (symptoms, emergency procedures, antidotes):
No other effect has been observed except those mentioned in the “Adverse reactions” section.

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).

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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

15. OTHER INFORMATION

Vaccine against feline leukaemia.

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.

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

Not all pack sizes may be marketed.

Approved 01 April 2022