ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Tray

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versifel FeLV,
suspension for injection for cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:
Inactivated feline leukaemia virus(FeLV) subtypes A, B and C (Kawakami-Theilen strain) including gp70 sub-unit antigen inducing anti-GP70 antibodies GMT ≥ 8.1 $\log_2$*

Adjuvants:
Quil A
Cholesterol
DDA
Carbomer

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

10 x 1 dose
25 x 1 dose

5. TARGET SPECIES

Cats

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Shake the vial before use.

Read the package leaflet before use.

Subcutaneous use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: month/year
Once opened, use immediately.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIAL, IF ANY

To be completed nationally.

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

For animal treatment only (ad. us. vet.)

14. "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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm: 42058/4164

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versifel FeLV
suspension for injection for cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Active substance:

Inactivated feline leukaemia virus (FeLV)	GMT ≥ 8.1 $\log_2$

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

1dose/1 mL

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP: month/year

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only. (ad.us.vet)

B. PACKAGE LEAFLET

Package leaflet for
Versifel FeLV, suspension for injection for cats

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

Marketing authorisation holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versifel FeLV,
suspension for injection for cats

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

Each dose of 1 mL contains:

Active substance:
Inactivated feline leukaemia virus (FeLV) subtypes A, B and C (Kawakami-Theilen strain) including gp70 sub-unit antigen inducing anti-GP70 antibodies GMT ≥ 8.1 $\log_2$*

* Geometric mean titre (GMT) as determined by mouse potency test

Adjuvants:

Quil A	20 μg
Cholesterol	20 μg
DDA (Dimethyl-diocatadecyl ammonium bromide)	10 μg
Carbomer	0.5 mg

Slightly opaque suspension

4. INDICATION(S)

For active immunization of susceptible cats from 9 weeks of age to reduce the number of cats infected with FeLV and presenting clinical signs of the related disease
No data are available in the studies to demonstrate protection against related clinical disease but prevention of infection is associated with protection against related clinical disease.

Onset of immunity occurs within four weeks of the completion of the primary vaccination course.
The duration of immunity is at least one year after the primary course and three years after the booster.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

Commonly, small subcutaneous swellings have occurred at the injection site, (diameter usually smaller than 10 mm, maximal diameter 20 mm) and very rarely may be associated with a brief period of discomfort and/or pain. The majority of these swellings resolve within a short period (2 weeks). A small proportion may remain detectable for 1 to 2 months however, by this time they are very small.

Commonly, following the first subcutaneous administration in the target species, transient increases in temperature could occur (up to 40.5°C after administration of an overdose); such temperature rises are however expected to be of short duration (resolving within 48 hours). Frequency and duration of any temperature rise is usually lower following subsequent administrations.

When administered concurrently or simultaneously with Zoetis' Versifel CVR transient increases in temperature (up to 40.5 °C) are common following first vaccination lasting up to 5 days.

Following the second dose administration, on rare occasions transient enlargements of the pre-scapular lymph nodes have been observed; such enlargements are small in size (0.5 cm diameter) and only detected upon palpation of the area following injection.

Very rarely, a brief period of general malaise or mild or moderate depression is observed immediately post vaccination but normally resolves within 24 hours; health of animals is not adversely affected.

Very rarely, digestive tract disorders such as: vomiting, diarrhoea or anorexia has been observed.

In very rare cases allergic reactions have been observed. In case of anaphylactic shock appropriate treatment should be administered.

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

7. TARGET SPECIES

Cats

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

Subcutaneous use

Primary vaccination:
Two 1 ml doses should be administered subcutaneously to cats from 9 weeks of age, with an interval of 3-4 weeks between doses.

Re-vaccination:
A single booster dose should be administered 1 year after the completion of the primary vaccination course. Thereafter a single booster dose should be administered to cats once every 3 years.

9. ADVICE ON CORRECT ADMINISTRATION

Shake the vial well immediately before use.

For concurrent vaccination with Zoetis' Versifel CVR, a single dose of Versifel FeLV should be administered as described above. A single dose of Zoetis' Versifel CVR should then be administered at a separate site via the subcutaneous route.

For simultaneous vaccination with Zoetis' Versifel CVR, the contents of a single vial of Zoetis'Versifel CVR is reconstituted with the contents of a single vial of Versifel FeLV in place of the diluent. Once mixed, the contents of the vial should appear as a slightly coloured (pink/orange) opaque suspension; the mixed vaccines should be injected immediately via the subcutaneous route.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use after the expiry date which is stated on the label.

Shelf-life after first opening the container: use immediately.

12. SPECIAL WARNINGS

Special warnings for each target species:

Only healthy animals should be vaccinated.
Do not vaccinate FeLV antigen positive cats. Therefore a test for presence of FeLV before vaccination is recommended.
No data are available for the efficacy of the product in presence of maternally derived antibodies.

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 in pregnant and lactating cats.

Interaction with other medicinal products and other forms of interaction:

Safety and efficacy data are available which demonstrate that this vaccine can be either mixed with Zoetis' Versifel CVR and administered at a single site or administered on the same day as Zoetis' Versifel CVR, but at different sites.
No data are available on the duration of immunity of Versifel FeLV when administered together with Versifel CVR, this should be taken into account when considering re-vaccination intervals.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medical product except the product 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):

Following the administration of an overdose a larger proportion of animals might be expected to show a transient rise in rectal temperature (up to 40.5°C). Such transient rises are however expected to be of short duration (resolving within 48 hours).

Frequency and duration of any temperature rise is usually lower following subsequent single dose administrations.

In the laboratory overdose study, in which a two times (2 ml) dose was administered, a larger proportion of animals developed a swelling at the injection site, (max. diameter up to 21 mm). The majority of these swellings resolved within a short period (within 2 weeks). A slightly larger proportion had swellings which remained detectable for 1 or 2 months however, by this time they were very small.

Incompatibilities:

Do not mix with any other veterinary medicinal product other than Versifel CVR.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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

15. OTHER INFORMATION

Pack sizes:
10 x 1 dose
25 x 1 dose

Not all pack sizes may be marketed.

Approved 25 October 2019