1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versifel FeLV,
suspension for injection for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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 $\geq$ 8.1 $\log_2$*

* As determined by mouse potency test (anti-gp70 antibodies, GMT denotes: geometric mean titre)

Adjuvants:

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

Slightly opaque suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None.

4.4 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 maternal derived antibodies.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

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)

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).

4.7 Use during pregnancy and lactation or lay

Do not use in pregnant and lactating cats.

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 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 medicinal 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.

4.9 Amounts to be administered and administration route

Subcutaneous use.
Shake the vial well immediately before use.

Primary vaccination:
Two doses of 1 mL should be administered subcutaneously to cats from nine 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.

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 should be 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.

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

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 an overdose, comprising double (2 ml) the recommended 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.

4.11 Withdrawal period

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Felidae, inactivated viral vaccines for cats.

ATC vet code: QI06AA01

Vaccination stimulates active immunity against FeLV infection in healthy cats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Quil A
Cholesterol
DDA (Dimethyl-dioctadecyl ammonium bromide)
Carbomer
Phosphate buffered saline

6.2 Incompatibilities

Safety and efficacy data are available which demonstrate that this vaccine can be mixed with, or administered at the same time as, Zoetis' Versifel CVR. Do not mix with any other veterinary medicinal product.

6.3 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.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Single dose type I (Ph. Eur.) glass vials, closed with rubber stoppers (Ph. Eur.) and sealed with aluminium caps.

Pack sizes:

Clear plastic tray containing 10 x 1 ml dose.
Clear plastic tray containing 25 x 1 ml dose.

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 products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

To be completed nationally.

8 MARKETING AUTHORISATION NUMBER

To be completed nationally.

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

To be completed nationally.

10 DATE OF REVISION OF THE TEXT

To be completed nationally.

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be completed nationally..