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.

Excipient:

Qualitative composition of excipients and other constituents
Phosphate buffered saline

Slightly opaque suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

For active immunisation 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: four weeks after the completion of the primary vaccination course.

Duration of immunity: one year after the primary course and three years after the booster.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.
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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cats:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1] Elevated temperature[2, 3]
Rare (1 to 10 animals / 10,000 animals treated):	Enlarged lymph node (localised)[4]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain Diarrhoea, Vomiting Allergic reaction, Anaphylactic shock[5] Anorexia, Depression, Malaise[6]

[1]Small (diameter usually smaller than 10 mm, maximal diameter 20 mm) very rarely 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.
[2]Expected to be of short duration (resolving within 48 hours). Frequency and duration of any temperature rise is usually lower following subsequent administrations.
[3]When administered concurrently or simultaneously with Zoetis' Versifel CVR transient increases in temperature (up to 40.5 °C) are frequently observed following first vaccination lasting up to 5 days.
[4]Transient enlargement of the pre-scapular lymph node following the second dose administration, such enlargements are small in size (0.5 cm diameter) and only detected upon palpation of the area following injection.
[5]If such a reaction occurs appropriate treatment should be administered.
[6]Normally resolves within 24 hours.

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

Pregnancy and lactation:

The use is not recommended during 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 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.

3.9 Administration routes and dosage

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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 twice the recommended dose (2 ml) 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.

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: QI06AA01

Vaccination stimulates active immunity against FeLV infection in healthy cats.

5. PHARMACEUTICAL PARTICULARS

5.1 Major 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.

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).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Single dose type I glass vials, closed with rubber stoppers 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.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Zoetis Belgium S.A

7. MARKETING AUTHORISATION NUMBER(S)

VPA10387/088/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: *01/02/2013.*

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

05/10/2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).