# SUMMARY OF PRODUCT CHARACTERISTICS

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

*To be completed nationally.*

## 7. MARKETING AUTHORISATION NUMBER(S)

*To be completed nationally.*

## 8. DATE OF FIRST AUTHORISATION

Date of first authorisation: *To be completed nationally.*

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

*To be completed nationally.*

## 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).

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CLEAR PLASTIC TRAY**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versifel FeLV suspension for injection.

## 2. STATEMENT OF ACTIVE SUBSTANCES

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 $\log_2$

## 3. PACKAGE SIZE

10 x 1 dose
25 x 1 dose

## 4. TARGET SPECIES

Cats.

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Subcutaneous use.

## 7. WITHDRAWAL PERIODS

## 8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

## 9. SPECIAL STORAGE PRECAUTIONS

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

## 10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

## 11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

## 12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

## 13. NAME OF THE MARKETING AUTHORISATION HOLDER

*To be completed nationally.*

## 14. MARKETING AUTHORISATION NUMBERS

*To be completed nationally.*

## 15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**VIAL (1 ML SUSPENSION)**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versifel FeLV

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

FeLV

1 ml/dose

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}

**B. PACKAGE LEAFLET**

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Versifel FeLV suspension for injection for cats

## 2. 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-diocatadecyl ammonium bromide) | 10 µg. |
| Carbomer | 0.5 mg. |

Slightly opaque suspension.

## 3. Target species

Cats.

## 4. Indications for use

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.

## 5. Contraindications

None.

## 6. Special warnings

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 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:
The use is not recommended during 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 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:
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.

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.

## 7. Adverse events

Cats:

| Common (1 to 10 animals / 100 animals treated): |
|---|
| Injection site swelling[1]<br>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<br>Diarrhoea, Vomiting<br>Allergic reaction, Anaphylactic shock (severe allergic reaction)[5]<br>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 product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

## 8. Dosage for each species, routes 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 periods

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 this veterinary medicinal product after the expiry date which is stated on the label and tray after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: use immediately.

## 12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

## 13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

## 14. Marketing authorisation numbers and pack sizes

*To be completed nationally.*

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.

## 15. Date on which the package leaflet was last revised

*To be completed nationally.*

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

## 16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:
*To be completed nationally.*

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

<Local representatives< and contact details to report suspected adverse reactions>:>
*To be completed nationally* if applicable.

## 17. Other information

Vaccination stimulates active immunity against FeLV infection in healthy cats.