SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versifel CVR

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substances:
Live attenuated feline enteritis (panleucopaenia) virus (FPV), Snow Leopard strain, minimum titre: $10^{3.0}$ $CCID_{50}$*

Live attenuated feline rhinotracheitis virus (FVR), strain FVRm, minimum titre: $10^{5.0}$ $CCID_{50}$*

Live attenuated calicivirus (FCV), strain F9, minimum titre: $10^{5.5}$ $CCID_{50}$*
* Cell culture infectious dose 50%

Solvent:
Water for injections.

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for solution for injection.

4. CLINICAL PARTICULARS

4.1. Target species

Cats from 9 weeks of age.

4.2. Indications for use, specifying the target species

For active immunisation of cats to reduce mortality and clinical signs of disease caused by feline enteritis (panleucopaenia) virus, to reduce clinical signs of disease caused by feline rhinotracheitis virus and to prevent clinical signs of disease and reduce infection caused by feline calicivirus.

Onset of immunity occurs by approximately 3 weeks after the last dose of the Basic Vaccination Scheme.
The duration of immunity is at least 12 months.

4.3. Contraindications

None.

4.4. Special warnings for each target species

Vaccinate healthy animals only.

The feline panleucopaenia virus and the feline calicivirus vaccinal strains may be shed from vaccinated animals for a number of days following vaccination. However, due to the low pathogenicity of these strains, it is not necessary to keep vaccinated animals separated from non-vaccinated animals.
Moderate to high levels of maternally derived antibodies (MDA) may interfere with the response to vaccination.

4.5. Special precautions for use

i) Special precautions for use in animals

None.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of accidental self-injection, wash the area immediately with water. If symptoms develop, seek medical attention showing a copy of the product literature.

4.6. Adverse reactions (frequency and seriousness)

On rare occasions, transient increases in rectal temperature, transient lameness and transient lethargy may be observed as well as soft painless swellings (<1 cm average) may occur in the first 24 hours after vaccination, which may be evident as painless hard nodules for up to 21 days after dosing.

On very rare occasions, an anaphylactic reaction may occur which may require appropriate symptomatic treatment (e.g. adrenaline).

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 in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- 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).

4.7. Use during pregnancy, lactation or lay

Do not use during pregnancy.

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 Versifel FeLV and administered at a single site or

administered on the same day as Versifel FeLV, but at different sites.

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

No data are available on the duration of immunity of Versifel CVR when administered together with Versifel FeLV, 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. Amount(s) to be administered and administration route

Reconstitute the lyophilisate fraction aseptically with the complete contents of the solvent provided. Shake and immediately inject the contents of the vial subcutaneously 1 ml per dose.

Basic vaccination
In cats aged nine weeks and over, two injections of Versifel CVR, 3 to 4 weeks apart will stimulate full active immunity.

Re-vaccination
A single 1 ml dose is required on an annual basis.

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

For simultaneous vaccination with Versifel FeLV, the contents of a single vial of 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.

Do not use chemically sterilised syringes or needles, as these might affect the effectiveness of the vaccine.

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

No reactions other than those listed in Section 4.6 are observed after an overdose administration.

4.11. Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Vaccination induces the active immunity in healthy cats against feline infectious enteritis (panleucopaenia) and respiratory disease due to feline rhinotracheitis virus and calicivirus.

ATCVet Code: QI06AD04.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Solvent:
Water for injections

6.2. Major Incompatibilities

Safety and efficacy data are available which demonstrate that this vaccine can be mixed with, or administered concurrently with Versifel FeLV. 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 reconstitution according to directions: use immediately.

6.4. Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C). Do not freeze.

6.5. Nature and composition of immediate packaging

The lyophilisate component and the solvent component are filled in 1 single dose glass vials Type I (Ph. Eur.). Both have a rubber stopper fulfilling Ph. Eur. requirements and an aluminium cap.

Boxes contain 25 glass vials of 1 dose containing the lyophilisate component and 25 glass vials of 1 ml containing the solvent.

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 medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
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Springfield Drive
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Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4163

9. DATE OF FIRST AUTHORISATION

12 February 2010

10. DATE OF REVISION OF THE TEXT

September 2021

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