PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing 25 x 1 dose lyophilisate and 25 x 1 ml solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versifel CVR

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose of Versifel CVR contains:
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 $10^{5.0}$ $CCID_{50}$* and live attenuated calicivirus (FCV), strain F9, minimum titre $10^{5.5}$ $CCID_{50}$*.
* Cell culture infectious dose 50%

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for solution for injection

4. PACKAGE SIZE

25 x 1 dose Versifel CVR
25 x 1 ml dose diluent

5. TARGET SPECIES

Cats from 9 weeks of age.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous injection.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP::
Once reconstituted use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.
POM-V

14. THE WORDS "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(S)

Vm 42058/4163

17. MANUFACTURER'S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial for lyophilisate of 1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versifel CVR

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Feline infectious enteritis, viral rhinotracheitis and calicivirus vaccine.

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch:
Once reconstituted use immediately.

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET:
Versifel CVR

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF 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 CVR

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

A lyophilisate fraction containing 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 $10^{5.0}$ $CCID_{50}$* and live attenuated feline calicivirus (FCV), strain F9, minimum titre $10^{5.5}$ $CCID_{50}$*
* Cell culture infectious dose 50%

4. INDICATION(S)

For the active immunisation of healthy 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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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).

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.

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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cats from 9 weeks of age.

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

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

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

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

9. ADVICE ON CORRECT ADMINISTRATION

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

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.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2 °C – 8 °C). Do not freeze.
For animal treatment only.
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP.
Shelf life after reconstitution according to directions: use immediately.

12. SPECIAL WARNING(S)

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.

Special precautions for use in animals:
None.

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.

Pregnancy:
Do not use during pregnancy.

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.

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.

Overdose (symptoms, emergency procedures, antidotes):
No reactions other than those listed above under 'Adverse Reactions' are observed after an overdose administration.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist 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

September 2021

15. OTHER INFORMATION

Versifel CVR is supplied in boxes of 25 vials containing the lyophilisate fraction, together with 25 vials of the solvent fraction.

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To be supplied only on veterinary prescription.

Vm 42058/4163

Approved: 22/09/21