SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Leukocell 2

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1ml) of Leukocell 2 contains the following

Active substances:
Inactivated sub-unit antigens (gp 70 and FOCMA) of feline leukaemia virus (FeLV) sub-types A, B and C: *minimum: 2266 ng/ml of gp70 antigen.*

Excipients:
Alhydrogel 2 % 50 µl
Quil A 25 µg
Thiomersal 0.115 mg (maximum)

See Section 6.1 for full list of excipients.

3. PHARMACEUTICAL FORM

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

Active immunisation of cats to reduce persistent viraemia and lymphoid tumours caused by FeLV infection, and thereby to reduce other diseases associated with FeLV infection.

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

Unhealthy animals should not be vaccinated.

The use of immunosuppressant drugs or procedures within one month of vaccination is contra-indicated.

4.4 Special warnings for each target species

If an anaphylactic reaction occurs, institute treatment according to the clinical signs using adrenaline or other appropriate medication.

Vaccination is of no known clinical value in cats with pre-existing FeLV infection, nor will it change the natural course of the disease.

The effect of maternally derived antibodies (MDA) on the response to vaccination is not known, but on the basis of published data and field use it is expected that the levels of MDA that will be present at 9 weeks of age will not 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 very rare occasions, soft painless swellings (<1 cm average) may occur after vaccination, which may be evident as painless hard nodules for up to 21 days. Transient increases in rectal temperature for up to 48 hours may also be observed. A small proportion of cats may show reduced activity for 1 or 2 days after vaccination and pain on injection (generally slight) may be observed. Rare occurrences of anaphylaxis, and gastro-enteric signs (emesis and diarrhoea) have been reported after vaccination.

When Leukocell 2 and Versifel CVR are administered simultaneously, incidence of local reactions may be increased.

4.7 Use during pregnancy, lactation or lay

Do not use in 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 administered on the same day as Versifel CVR (see Section 4.9). 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 decided on a case by case basis.

4.9 Amounts to be administered and administration route

Shake the vial well immediately before use, and administer the entire contents (1 ml) by subcutaneous injection.

Basic vaccination
In cats aged 9 weeks and more, two doses should be given, with an interval of 3-4 weeks.
If simultaneous immunisation against feline infectious enteritis (panleucopaenia) and respiratory disease due to feline viral rhinotracheitis (FVR) virus and calicivirus is required, Leukocell 2 can be used in place of the diluent to reconstitute Versifel CVR (freeze-dried feline infectious enteritis, viral rhinotracheitis and calicivirus vaccine, living), using the reconstitution method described in the product information for Versifel CVR. Once mixed, the vaccines should be injected immediately via the subcutaneous route.

Re-vaccination
Annual booster vaccination is recommended.

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 FeLV infection.

ATC Vet Code – QI06AA01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Alhydrogel 2%
Quil A
Thiomersal
Water for injection
Gentamycin

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product other than Versifel CVR (freeze-dried feline infectious enteritis, viral rhinotracheitis and calicivirus vaccine, living). See Section 4.9 for further information.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 1 year.

6.4 Special precautions for storage

Store and transport between 2°C and 8°C. Do not freeze.

6.5 Nature and composition of immediate packaging

Single dose glass vials Type I (Ph Eur), with a rubber stopper (Ph Eur compliant) and an aluminium cap.

Cartons contain 25 glass vials of Leukocell™ 2.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Dispose of waste materials by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

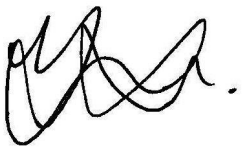
Vm 42058/4177

9. DATE OF FIRST AUTHORISATION

28 October 2005

10. DATE OF REVISION OF THE TEXT

May 2020



Approved: 01 May 2020