

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Leukocell 2 – Outer Label
25x 1ml dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Leukocell 2

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of Leukocell 2 contains inactivated sub-unit antigens (gp70 and FOCMA) of feline leukaemia virus (FeLV) sub-types A, B and C, minimum 2266 ng/ml of gp70 antigen.

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

25 x 1 ml dose

5. TARGET SPECIES

Cats

6. INDICATION(S)

For the active immunisation of healthy cats against FeLV injection.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Give by subcutaneous injection.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

For full instructions and warnings see package leaflet.

10. EXPIRY DATE

Exp. date:

11. SPECIAL STORAGE CONDITIONS

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

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

For full instructions and warnings see package leaflet.

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

For animal treatment only.

POM-

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

Keep out of reach and sight 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 42058/4177

17. MANUFACTURER’S BATCH NUMBER

Batch No

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Leukocell 2 – Vial Label
1ml dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Leukocell 2

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated adjuvanted sub-unit feline leukaemia virus vaccine.
Contains 0.01% w/v thiomersal as preservative.

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

Give by SC injection

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch No:

7. EXPIRY DATE

Expiry date:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
Keep out of reach and sight of children.
Store and transport at 2-8°C. Do not freeze.
Vm 42058/4117
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B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Leukocell 2

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Leukocell 2
Inactivated, adjuvanted sub-unit feline leukaemia virus (FeLV) vaccine.

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

A solution for injection containing inactivated sub-unit antigens (gp70 and FOCMA) of feline leukaemia virus (FeLV) subtypes A, B and C, minimum 2266 ng/ml of gp70 antigen. Also contains Alhydrogel 2% 50µl, Quil A 25µg, Thiomersal 0.115mg (maximum), water for injection to 1 ml and traces of gentamycin.

4. INDICATION(S)

For the active immunisation of healthy 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.

5. CONTRAINDICATIONS

Do not vaccinate unhealthy or pregnant animals.

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

6. ADVERSE REACTIONS

On very rare occasions, soft painless swellings (<1cm 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.

No reactions other than those listed above have been observed after an accidental overdose.

7. TARGET SPECIES

Cats.

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

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

Basic Vaccination Scheme:

In cats aged 9 weeks and over, two doses should be given, with an interval of 3-4 weeks.

Re-vaccination:

Annual booster vaccination is recommended.

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.

9. ADVICE ON CORRECT ADMINISTRATION

Shake the vial well immediately before use.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach and sight of children.

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

12. SPECIAL WARNING(S)

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

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

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.

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

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day as Versifel CVR. 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.

Operator warning:

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.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

May 2020

15. OTHER INFORMATION

For animal treatment only.

LEGAL CATEGORY

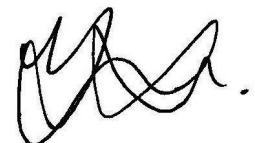
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PACKAGE QUANTITIES

Packs containing 25 doses of Leukocell 2. Packs of disposable syringes with needles are also available.

MARKETING AUTHORISATION NUMBER

Vm 42058/4177



Approved: 01 May 2020