PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felocell CVR

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose of Felocell CVR contains:

Live attenuated feline enteritis (Panleucopaenia) virus (FPV), Snow Leopard strain, minimum titre 103.0 CCID50*, and live attenuated calicivirus (FCV), strain F9, minimum titre 105.5 CCID50*.

Diluent: Water for injection.
* Cell culture infectious dose-50

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for solution for injection

4. PACKAGE SIZE

25 x 1 dose Felocell CVR

25 x 1 ml dose diluent

5. TARGET SPECIES

Cats

6. INDICATION(S)

For the active immunisation of healthy cats against diseases caused by feline infectious enteritis (panleucopaenia) virus, feline rhinotracheitis virus and feline calicivirus.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Give by subcutaneous injection immediately after reconstitution.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

For full instructions and warnings see package leaflet.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Animal Health,
Eli Lilly and Company Ltd,
Lilly House, Priestley Road,
Basingstoke, Hampshire,
RG24 9NL

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00006/4123

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felocell 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

Give by SC injection

5. WITHDRAWAL PERIOD

N/A

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

MA Holder:
Elanco Animal Health
Eli Lilly and Company Ltd
Lilly House, Priestley Road
Basingstoke, Hampshire
RG24 9NL
Manufacturing Authorisation Holder
responsible for batch release:
Zoetis Belgium
Rue Laid Burniat 1
Louvain-laNeuve
B-1348 Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felocell CVR

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

A freeze-dried fraction containing live attenuated feline enteritis (panleucopaenia) virus (FPV), Snow Leopard strain, minimum titre 103.0 CCID50, live attenuated feline rhinotracheitis virus (FVR), strain FVRm, minimum titre 105.0 CCID50 and live attenuated feline calicivirus (FCV), strain F9, minimum titre 105.5 CCID50, supplied with a vial of water for injection for reconstitution.
* Cell culture infectious dose-50
Also contains traces of neomycin and gentamycin.

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

Do not vaccinate unhealthy or pregnant animals.
On rare occasions, transient increases in rectal temperature, transient lameness and transient lethargy may be observed as well as soft

painless swellings (<1cm 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).
No reactions other than those listed above have been observed after an accidental overdose.
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.
When Felocell CVR and Leukocell 2 are administered simultaneously, incidence of local reactions may be increased.
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.

6. ADVERSE REACTIONS

7. TARGET SPECIES

Cats

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

Reconstitute the freeze-dried vaccine aseptically with the entire contents of the diluent provided. Shake and immediately inject the contents of the vial subcutaneously, 1 ml per dose. Do not use chemically sterilised syringes or needles, as these might affect the response of the vaccine.
Basic Vaccination Scheme:
In cats aged nine weeks and over, two injections of Felocell 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.
If simultaneous immunisation against feline leukaemia virus (FeLV) is required, Felocell CVR can be reconstituted with Leukocell 2 (inactivated, adjuvanted sub-unit FeLV vaccine) in place of the diluent, using the reconstitution method described above. Once mixed, the vaccines should be injected immediately via the subcutaneous route.

9. ADVICE ON CORRECT ADMINISTRATION

Do not mix with any other veterinary medicinal product except

the diluent provided for reconstitution or Leukocell 2 (inactivated, adjuvanted sub-unit FeLV vaccine).
Safety and efficacy data are available which demonstrates that this vaccine can be administered concurrently with Leukocell 2 (Pfizer's inactivated feline leukaemia vaccine). 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.

10. WITHDRAWAL PERIOD(S)

N/A

11. SPECIAL STORAGE PRECAUTIONS

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

12. SPECIAL WARNING(S)

<User Warnings>

For Animal Treatment Only

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

22 July 2013

15. OTHER INFORMATION>

POM-V UK Authorised Veterinary Medicinal Product.

Vm 00006/4123

Approved: 05/01/2018