SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FELOCELL™ CVR

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of Felocell CVR (1 ml) contains the following:

Active substance(s)
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*

Live attenuated Calicivirus (FCV), strain F9, minimum titre: 105.5 CCID50*
*Cell culture infectious dose-50

Diluent:
Water for injection.

For 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

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

Unhealthy animals should not be vaccinated.

4.4 Special warnings for each target species

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 21days after dosing.

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

When Felocell CVR and Leukocell 2 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 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.

4.9 Amounts to be administered and administration route

Reconstitute the freeze-dried vaccine aseptically with the complete contents of the diluents 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 Felocell CVR, 3 to 4 weeks apart will stimulate full active immunity.

Re-vaccination
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.

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.

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6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Neomycin
Gentamycin

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product except the diluent provided for reconstitution or Leukocell 2 (inactivated, adjuvanted sub-unit FeLV vaccine).

6.3 Shelf life

Two years
After reconstitution - use immediately.

6.4. Special precautions for storage

Store and transport the freeze-dried component and the diluent between 2°C and 8°C. Do not freeze.

6.5 Nature and composition of immediate packaging

The freeze-dried component and the liquid component are filled in 1 monodose glass vials Type I (Ph. Eur.). Both have a rubber stopper fulfilling Ph. Eur. requirements and an aluminium cap.

Cartons contain 25 glass vials of 1 monodose containing the freeze-dried component and 25 glass vials of 1 ml containing the diluent.

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

Elanco Animal Health
Eli Lilly & Company Limited
Lilly House
Priestly Road
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Hampshire
RG24 9NL

8. MARKETING AUTHORISATION NUMBER

Vm 00006/4123

9. DATE OF RENEWAL OF THE AUTHORISATION

28 October 2010

10. DATE OF REVISION OF THE TEXT

December 2010