

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

FELOCELL CVR.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose (when reconstituted) contains:

Active substance(s)

Live attenuated feline enteritis (panleucopenia) virus (FPV), Snow Leopard strain

minimum : $10^{3.0}$ *CCID₅₀

Live attenuated feline rhinotracheitis virus (FVR), strain FVRm

minimum : $10^{5.0}$ CCID₅₀

Live attenuated Calicivirus (FCV), strain F9

minimum : $10^{5.5}$ CCID₅₀

*CCID₅₀ = Cell culture infectious dose

Excipients:

For a 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

Felocell CVR is a live attenuated vaccine designed to reduce the clinical signs of disease caused by feline enteritis (panleucopenia) virus, feline rhinotracheitis virus and calicivirus in cats. The onset of immunity is from 3 weeks post-vaccination and lasts for 1 year.

4.3 Contraindications

Unhealthy animals should not be vaccinated.

4.4 Special warnings for each target species

Do not vaccinate animals for at least one month after cessation of corticosteroid treatment. Due to the nature of post-vaccination viral shedding, it is advised that vaccinated kittens are kept away from pregnant queens for a period of three weeks.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the medicinal product to animals

In the case of accidental self-injection seek medical advice immediately and show the package insert or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

On rare occasions, transient increases in rectal temperature, transient lameness and transient lethargy may be observed. In addition, soft painless swellings (<1 cm in average) at the site of injection may occur in the first 24 hours after vaccination, which may progress to painless hard nodules and persist for up to 21 days after administration. On very rare occasions, an anaphylactic reaction may occur which may require appropriate symptomatic treatment (e.g. adrenaline).

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

No information is available on the safety and efficacy from concurrent administration of this vaccine with any other. It is therefore recommended that no other vaccine should be administered within 14 days before or after vaccination with Felocell CVR.

4.9 Amounts to be administered and administration route

Dosage and route of administration :

Reconstitute the freeze-dried vaccine aseptically with the complete contents of the diluent 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.

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 adverse reactions, other than those listed in Section 4.6, are expected following administration of up to 10 times the recommended dose.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code – QI06AD04

Vaccination induces the active immunity in healthy cats against feline infectious enteritis (panleucopenia) and respiratory disease due to feline rhinotracheitis virus and calicivirus.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Modified Eagles medium
Dextran 40
Casein hydrolysate
Lactose
Sorbitol (70% solution)
Sodium hydroxide
Water for Injection

6.2 Incompatibilities

Do not mix the product with other medicinal products except for the solvent provided for reconstitution.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after reconstitution according to directions: use immediately.

6.4 Special precautions for storage

Lyophilisate: Store in a refrigerator (+2 °C to +8 °C). Protect from light. Do not freeze.
Solvent: Store in a refrigerator (+2 °C to 8 °C). Do not freeze.

6.5 Nature and composition of immediate packaging

The lyophilisate and the solvent are filled in Type I glass vials. Each vial is sealed with a rubber stopper and aluminium cap.
Cartons contain 25 single-dose glass vials of lyophilisate and 25 x 1 ml vials of solvent.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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 Ltd.,
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10047/021/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation 28th May 2004

Date of last renewal 27th May 2009

10 DATE OF REVISION OF THE TEXT

July 2014