SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Feligen® RCP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Freeze-Dried component

formula and titre per dose

- Live feline calicivirosis (strain F9) ……..	$10^{4.6}$	- $10^{6.1}$	$TCID_{50}$
- Live feline viral-rhinotracheitis virus (strain F2) ……..	$10^{5.0}$	- $10^{6.6}$	$TCID_{50}$
- Live feline viral-panleucopenia virus (strain LR 72) …	$10^{3.7}$	- $10^{4.5}$	$TCID_{50}$

2.2 Diluent

Water for injection ……... 1 ml

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection after reconstitution of the freeze-dried component in the diluent.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

The vaccine is intended for the active immunisation of healthy cats of minimum 9 weeks of age against:
- feline calicivirosis and feline viral rhinotracheitis to reduce clinical signs and viral excretion;
- feline panleucopenia to prevent leucopenia and to reduce clinical signs.

Onset of immunity is established four weeks after vaccination for calici virus and rhinotracheitis and three weeks for panleucopenia virus. This immunity lasts for 12 months.

4.3 Contraindications

None.

4.4 Special warnings for each target species

High level of maternal antibodies can interfere with the response to vaccination. Maternally derived antibodies, especially those against feline panleucopenia virus, can negatively influence the immune response to vaccination.

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals

i. Special precautions for use in animals

Vaccinate only healthy animals.

ii. Special precautions for the person administering the veterinary medicinal product to animals

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

4.6 Adverse reactions (frequency and seriousness)

Some transient post-vaccinal digestive disturbances were very commonly observed in safety studies. A slight and transient oedema which disappears spontaneously within 2 days was commonly observed during the days following vaccination in safety studies. Some transient and self-resolving post-vaccinal signs such as a slight hyperthermia and lethargy were commonly observed in safety studies.
Hypersensitivity reactions (e.g. emesis, diarrhoea, dyspnoea, allergic oedema) have been reported in very rare cases from spontaneous reports.
In case of such an allergic or anaphylactic reaction, appropriate symptomatic treatment should be administered.
As reported in the literature, after the use of any vaccine containing a Feline Calicivirus component, febrile limping syndrome reactions may occur very rarely in kittens.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and/or efficacy data are available which demonstrate that this vaccine can be mixed with Leucogen. No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products 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 gently the vial after reconstitution of the freeze-dried component in the diluent. Administer immediately *via* the subcutaneous route 1 dose of Feligen® RCP according to the following regimen of vaccination.

- Basic vaccination scheme:
  - a first injection into cats from minimum 9 weeks of age;
  - a second injection 3 to 4 weeks later.
  - Maternally derived antibodies can negatively influence the immune response to vaccination.
  - In such cases where maternally derived antibodies are expected, a third injection may be appropriate from 15 weeks of age.
- Re-vaccination scheme: annual re-vaccination of cats

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No undesirable effects have been seen after the administration of an overdose of Feligen® RCP except those indicated in section 4.6 Adverse reactions.

4.11 Withdrawal period

Not applicable

5. IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QI06AD04

Stimulation of the active immunity against feline calicivirus, feline rhinotracheitis virus and feline panleucopenia virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium hydroxide
Lactose monohydrate
L-glumatic acid
Potassium dihydrogen phosphate
Dipotassium phosphate
Gelatin
Water for injections
Sterile diluent

6.2 Incompatibilities

Safety and/or efficacy data are available which demonstrate that this vaccine can be mixed and administered with Leucogen. Do not mix with any other veterinary medicinal product, except the diluent supplied for use with the product or Leucogen.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
The product should be used immediately after reconstitution.

6.4 Special precautions for storage

Store and transport at 2°C-8°C. Protect from light. Do not freeze.
Use immediately after reconstitution.

6.5 Nature and composition of immediate packaging

Feligen® RCP – 3 ml glass type-1 vial containing freeze-dried attenuated live viral components stopped with an elastomer stopper.

Diluent – 3 ml glass type-1 vial containing 1 ml of water for injection stopped with an elastomer stopper.

Pack sizes : 10 x 1 and 50 x 1 dose

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Virbac
1ère Avenue – 2065m – L.I.D.
06516 Carros Cedex
France

8. MARKETING AUTHORISATION NUMBER

Vm 05653/4048

9. DATE OF FIRST AUTHORISATION

28 October 2005

10. DATE OF REVISION OF THE TEXT

February 2018

Approved 20 February 2018