ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

BOX 0F 50 AND 10 DOSES

Feligen®RCP

Solution for injection vaccine against feline rhinotracheitis-virus, feline calici-virus and feline panleucopenia-virus infections.

50 x 1 dose / 10 x 1 dose

- PRESENTATION

FELIGEN® RCP is a freeze-dried vaccine containing live attenuated strains of feline panleucopenia virus, feline rhinotracheitis virus and feline calici virus for the active immunisation of healthy cats of minimum 9 weeks of age by subcutaneous injection.

- COMPOSITION

Active substances: (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) ($10^{3.7}$ - $10^{4.5}$ $TCID_{50}$)

Diluent: Water for injection 1 ml

- PHARMACEUTICAL PRECAUTIONS

The vaccine should be stored and transported in the original packaging between +2 °C and +8 °C. Protect from light. Do not freeze. Use immediately after reconstitution.

- DOSAGE AND ADMINISTRATION, WARNINGS, DISPOSAL ADVICE

Read the package leaflet before use.

Vm 05653/4048

POM - V

To be supplied only on veterinary prescription.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

FOR ANIMAL TREATMENT ONLY

- M.A.H.:

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FREEZE DRIED COMPONENT LABEL

Feligen® RCP

Solution for subcutaneous injection

- 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}$).

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

SQ use in healthy cats only.

For animal treatment only.

M.A.H.: Virbac.

Distributed by Virbac Ltd

POM-V

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1 dose

DILUENT LABEL

Feligen® RCP Sterile diluent

1mL

Transfer contents aseptically to reconstitute freeze-dried vaccine. Subcutaneous injection for cats.

FOR ANIMAL TREATMENT ONLY

POM-V

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B. PACKAGE LEAFLET

PACKAGE LEAFLET:

FELIGEN® RCP solution for injection after reconstitution of the freeze-dried component in the diluent

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

Virbac
1ère Avenue 2065m LID
06516 Carros Cedex
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FELIGEN® RCP

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

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) … $10^{3.7}$ - $10^{4.5}$ $TCID_{50}$

Diluent

Water for injection ……... 1 ml

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

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).>

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

CATS

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

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

9. ADVICE ON CORRECT ADMINISTRATION

Vaccinate only healthy animals

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C)
Do not freeze
Protect from light.
Use immediately after reconstitution.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. SPECIAL WARNING(S)

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.

Special precautions to be taken by the person administering the veterinary 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.

Pregnancy and lactation:
Do not use during pregnancy and lactation

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.

Overdose (symptoms, emergency procedures, antidotes):
No undesirable effects have been seen after the administration of an overdose of Feligen® RCP except those indicated in section 6. Adverse reactions
Incompatibilities:
Do not mix with any other veterinary medicinal product, except the diluent supplied for use with the product or Leucogen.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2017

Detailed information on this veterinary medicinal product is available on the website of the Veterinary Medicines Directorate.
https://www.gov.uk/government/organisations/veterinary-medicines-directorate

15. OTHER INFORMATION

Pack sizes: 10 x 1 and 50 x 1 dose
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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U.K. authorised veterinary medicinal product.
FOR ANIMAL TREATMENT ONLY

Distributed by
VIRBAC LTD
Suffolk, IP30 9UP
U.K.

Approved 20 February 2018