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Leucofeligen FeLV/RCP (*Feline calicivirosis, feline viral rhinotracheitis, feline panleucopenia (live attenuated) and feline leukaemia (inactivated) vaccine*)

An overview of Leucofeligen FeLV/RCP and why it is authorised in the EU

What is Leucofeligen FeLV/RCP and what is it used for?

Leucofeligen FeLV/RCP is a vaccine used to protect cats from eight weeks of age against the following diseases:

- feline calicivirosis (a flu-like illness with inflammation of the mouth caused by a calicivirus);
- feline viral rhinotracheitis (a flu-like illness caused by a herpesvirus);
- feline panleucopenia (a serious illness causing bloody diarrhoea and a fall in white blood cell counts caused by a parvovirus);
- feline leukaemia (an illness affecting the immune system causing loss of appetite, weight loss, poor fur condition, fever, pale gums and diarrhoea caused by a retrovirus).

The vaccine helps to reduce the signs of these diseases. It also prevents feline panleucopenia and persistent viraemia for feline leukaemia (the presence of feline leukaemia virus in the blood).

The vaccine contains live feline viruses that have been attenuated (weakened) so they do not cause disease: feline calicivirus (strain F9), viral rhinotracheitis virus (strain F2) and feline panleucopenia virus (strain LR 72). It also contains a protein of feline leukaemia virus (FeLV).

How is Leucofeligen FeLV/RCP used?

Leucofeligen FeLV/RCP is given to kittens as two injections under the skin. The first injection is given when the kitten is about eight weeks old, and the second three or four weeks later. One year after the initial vaccination a booster vaccination should be given.

Protection against panleucopenia and leukaemia starts 3 weeks after the second injection, protection against calicivirosis starts 3 weeks after first vaccine injection and protection against viral rhinotracheitis starts 4 weeks after the second injection. Protection against leukaemia lasts for 3 years once a booster has been given and lasts for one year for calicivirosis, panleucopenia and viral



rhinotracheitis. Therefore, older cats need revaccination with Leucofeligen FeLV/RCP only every 3 years, with annual revaccination in intervening years with the vaccine Feligen RCP to protect against calicivirocrosis, rhinotracheitis and panleucopenia.

Leucofeligen FeLV/RCP is available as two vials, one containing a white powder pellet and one containing a liquid. The contents of the two vials are mixed together before use to make up a suspension for injection. The vaccine can only be obtained with a prescription.

For more information about using Leucofeligen FeLV/RCP, see the package leaflet or contact your veterinarian or pharmacist.

How does Leucofeligen FeLV/RCP work?

Leucofeligen FeLV/RCP is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against diseases. Leucofeligen FeLV/RCP contains small amounts of the three weakened viruses as listed above and a protein from the outer layer of FeLV called 'envelope p45 protein'. The FeLV protein used in the vaccine is not extracted from viruses but is made in a bacterium using 'recombinant DNA technology'.

When a cat is given the vaccine, the immune system recognises the weakened viruses and the FeLV proteins as 'foreign' and makes antibodies against them. In the future, the cat's immune system will be able to produce antibodies more quickly when it is exposed to the disease-causing forms of the viruses. This will help to protect against the diseases caused by these viruses. The vaccine also contains aluminium hydroxide and extract of *Quillaja saponaria* as adjuvants (ingredients that strengthen the immune response).

What benefits of Leucofeligen FeLV/RCP have been shown in studies?

Because Leucofeligen FeLV/RCP is made up of two vaccines that have been available in the European Union (EU) since the 1980s (Feligen RCP and Leucogen), the company used data from studies carried out with these vaccines to support the use of Leucofeligen FeLV/RCP. Leucofeligen FeLV/RCP has been examined in two main 'field' studies involving kittens aged eight to nine weeks. Further studies were carried out under laboratory conditions to confirm the other benefits of vaccination.

The studies showed that Leucofeligen FeLV/RCP provided protection against the diseases listed above as measured by the presence of antibodies against the viruses in the vaccinated kittens' blood. In addition, it reduced the excretion of feline viral rhinotracheitis viruses, prevented a fall in white blood cell counts in feline panleucopenia and prevented FeLV from remaining in the blood.

A laboratory study in which cats were exposed to feline leukaemia virus confirmed that following the first annual booster vaccination cats were protected for a three year period against leukaemia.

What are the risks associated with Leucofeligen FeLV/RCP?

The most common side effects with Leucofeligen FeLV/RCP (which may affect up to 1 in 10 cats) are a moderate and short-lived local reaction (≤ 2 cm) after the first injection which resolves without treatment within 3 to 4 weeks, raised body temperature (lasting 1 to 4 days), apathy (listlessness) and digestive disturbances.

Leucofeligen FeLV/RCP should not be used in pregnant cats. Its use is not recommended in cats nursing kittens.

For the full list of side effects and restrictions with Leucofeligen FeLV/RCP, see the package leaflet.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or label shown to the doctor.

Why is Leucofeligen FeLV/RCP authorised in the EU?

The European Medicines Agency decided that Leucofeligen FeLV/RCP's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about Leucofeligen FeLV/RCP

Leucofeligen FeLV/RCP received a marketing authorisation valid throughout the EU on 25 June 2009.

Further information on Leucofeligen FeLV/RCP can be found on the Agency's website: [ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports](http://ema.europa.eu/Find_medicine/Veterinary_medicines/European_public_assessment_reports).

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