



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## EPAR summary for the public

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### Purevax RCP FeLV

Feline viral rhinotracheitis, feline panleucopenia (live attenuated), feline leukaemia and feline calicivirosis (inactivated) vaccine

This is a summary of the European public assessment report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use.

This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the scientific discussion (also part of the EPAR).

#### What is Purevax RCP FeLV?

Purevax RCP FeLV is a veterinary vaccine that contains:

- attenuated (weakened) feline rhinotracheitis herpesvirus (FHV F2 strain),
- inactivated (killed) calicivirosis antigens (FCV 431 and G1 strains),
- attenuated feline panleucopenia virus (PLI IV),
- feline leukaemia virus (FeLV) recombinant canarypox virus (vCP97).

Purevax RCP FeLV is available as a lyophilisate (freeze-dried pellet) and solvent that are made up into a suspension for injection.

#### What is Purevax RCP FeLV used for?

Purevax RCP FeLV is used to vaccinate cats from the age of 8 weeks against:

- feline viral rhinotracheitis (a flu-like illness caused by a herpesvirus),
- feline calicivirosis (a flu-like illness with inflammation of the mouth caused by a calicivirus),
- feline panleucopenia (a serious illness causing bloody diarrhoea caused by a parvovirus),
- feline leukaemia (an illness affecting the immune system caused by a retrovirus, feline leukaemia virus).

The vaccine helps to reduce the symptoms of the diseases. It also helps to reduce viral excretion in case of calicivirus infection for one year after vaccination. It can also prevent death due to panleucopenia and prevent FeLV from remaining in the blood.

The vaccine is given as two doses injected under the skin. The first injection should be given in kittens aged



at least eight weeks, with a second injection three to four weeks later. If the kitten has high levels of antibodies received from the mother in the womb and in the milk, the first vaccination should be delayed until 12 weeks of age. The cat should be revaccinated for all components one year after the first vaccination course, then every year for feline leukaemia, and every three years for rhinotracheitis, calicivirosis and panleucopenia.

### **How does Purevax RCP FeLV work?**

Purevax RCP FeLV is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Purevax RCP FeLV contains small amounts of weakened or killed viruses that cause feline viral rhinotracheitis, calicivirosis and panleucopenia. To protect against feline leukaemia the vaccine contains two genes from the FeLV called env and gag, which have been inserted into another vector (carrier) virus called canarypox using 'recombinant DNA technology'. The canarypox viruses do not spread or multiply in the cat but they do produce proteins from the FeLV genes.

When a cat is given the vaccine, the immune system recognises the weakened or killed viruses and the FeLV proteins as 'foreign' and makes antibodies against them. In the future, the immune system will be able to produce antibodies more quickly when it is again exposed to the viruses. The antibodies will help to protect against the diseases caused by these viruses. When exposed to any of these viruses later in life, the cat will either not become infected or have a much less serious infection.

### **How has Purevax RCP FeLV been studied?**

The effectiveness of Purevax RCP FeLV has been studied in several trials in laboratory conditions where cats were vaccinated and infected with herpesvirus, calicivirus, parvovirus or leukaemia virus. In the field the studies of Purevax RCP FeLV looked at the basic vaccination schedule (2 injections 3–4 weeks apart) and at the booster vaccination. They included young and adult cats of various breeds, but not young kittens. The main measure of effectiveness was the level of antibodies in the blood against the viruses in the vaccine, with the exception of the FeLV component, whose effectiveness in preventing infection had already been demonstrated in other studies.

### **What benefit has Purevax RCP FeLV shown during the studies?**

In laboratory conditions Purevax RCP FeLV was demonstrated to provide protection against the diseases listed above. In the field study of basic vaccination there was an increase in antibodies against feline rhinotracheitis herpesvirus, calicivirus infection, and feline panleucopenia viruses. In the study looking at booster vaccination, antibody levels against rhinotracheitis herpesvirus, calicivirus infection and feline panleucopenia remained stable at a high level or increased slightly.

### **What is the risk associated with Purevax RCP FeLV?**

Occasionally, cats will develop temporary apathy (loss of interest in surroundings) and anorexia (loss of appetite), as well as hyperthermia (elevated body temperature) lasting for one or two days. There may be a local reaction at the injection site, with slight pain on touching, itching or oedema (swelling), which disappears within one or two weeks. For a full list of the side-effects reported with Purevax RCP FeLV, see the package leaflet.

Purevax RCP FeLV should not be used in pregnant cats.

## **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 the label shown to the doctor.

## **Why has Purevax RCP FeLV been approved?**

The CVMP concluded that the benefits of Purevax RCP FeLV exceed the risks for the active immunisation of cats aged eight weeks or older against the diseases listed above approved indications and recommended that Purevax RCP FeLV be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion 6 of this EPAR.

## **Other information about Purevax RCP FeLV:**

The European Commission granted a marketing authorisation valid throughout the European Union, for Purevax RCP FeLV on 23 February 2005. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in January 2015.