

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

PUREVAX RCCH

EPAR summary for the public

This document 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 RCCh?

Purevax RCCh is a vaccine containing the following active substances:

- attenuated (weakened) feline rhinotracheitis herpesvirus (FHV F2 strain),
- inactivated (killed) caliciviruses antigens (FCV 431 and G1 strains),
- attenuated *Chlamydomonas felis* (905 strain).

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

What is Purevax RCCh used for?

Purevax RCCh is used to vaccinate cats from the age of 8 weeks against the following diseases:

- feline viral rhinotracheitis (a flu-like illness caused by a herpesvirus),
- feline caliciviruses (a flu-like illness with inflammation of the mouth caused by a calicivirus),
- chlamydiosis (a flu-like illness caused by the bacterium *C. felis*).

The vaccine helps to reduce the symptoms of the diseases. It also helps to reduce viral excretion in case of calicivirus infection.

After Purevax RCCh has been made up, 1 ml is injected under the skin. The first injection should be given in cats aged at least eight weeks, with a second injection three to four weeks later. If the cat has high levels of antibodies inherited from the mother, 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 rhinotracheitis, caliciviruses and chlamydiosis.

How does Purevax RCCh work?

Purevax RCCh is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against diseases. Purevax RCCh contains small amounts of weakened or killed viruses and bacteria that cause the diseases listed above.

When a cat is given the vaccine, the immune system recognises the weakened or killed viruses and the weakened bacteria 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 or bacteria. The antibodies will help to protect against the diseases caused by these viruses or bacteria. 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 RCCh been studied?

The effectiveness of Purevax RCCh has been studied in several trials in laboratory conditions where cats were vaccinated and infected with virulent herpesvirus, calicivirus or *C. felis*. In the field, the studies of Purevax RCCh looked at the basic vaccination schedule (2 injections 3-4 weeks apart) and at the booster vaccination (only one injection). 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 and bacteria in the vaccine.

What benefit has Purevax RCCh shown during the studies?

In laboratory conditions Purevax RCCh 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 and calicivirus infection. It was not possible to detect a rise in antibodies against *C. felis* because of high levels of antibodies in the cats at the beginning of the study. In the study looking at booster vaccination, antibody levels against rhinotracheitis herpesvirus, calicivirus infection and *C. felis* remained stable at a high level or increased slightly.

What is the risk associated with Purevax RCCh?

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 RCCh, see the Package Leaflet. Purevax RCCh 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 seek medical advice immediately and show the Package Leaflet or the label to the doctor. The vaccine should not be handled by people with a weak immune system. If self-injection does occur in these people, tell the doctor that self-injection with a living chlamydial vaccine has occurred.

Why has Purevax RCCh been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Purevax RCCh exceed the risks for the active immunisation of cats aged eight weeks or older against the diseases listed above, and recommended that Purevax RCCh be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

Other information about Purevax RCCh:

The European Commission granted a marketing authorisation valid throughout the European Union for Purevax RCCh to MERIAL on 23 February 2005.

This summary was last updated on 25 January 2008.

Medicinal product no longer authorised