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**EPAR summary for the public**

# Purevax Rabies

Recombinant vaccine against rabies infection

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 Rabies?

Purevax Rabies is a vaccine that contains rabies recombinant canarypox virus (vCP65). Purevax Rabies is a liquid suspension for injection.

## What is Purevax Rabies used for?

Purevax Rabies is used to vaccinate cats from 12 weeks of age to protect against rabies infection.

A 1 ml dose of Purevax Rabies is injected under the skin. The first injection should be given in cats aged at least 12 weeks. Protection starts at the latest four weeks after the injection and lasts for a year. The cats should be revaccinated every year.

## How does Purevax Rabies work?

Purevax Rabies is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against diseases. The vaccine strain vCP65 in Purevax Rabies is a 'carrier' canarypox virus that has been given a gene that makes it able to produce part of a rabies virus called 'glycoprotein G'. The canarypox viruses do not spread or multiply in the cats but they do produce the glycoprotein G of the rabies virus.

When a cat is given the vaccine, the immune system recognises the rabies glycoprotein G as 'foreign' and makes antibodies against it. In the future, the immune system will be able to produce antibodies

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more quickly when it is exposed to rabies, and this helps to protect against mortality due to rabies infection.

## How has Purevax Rabies been studied?

A number of studies, including laboratory studies and field trials, were performed in kittens and cats looking at Purevax Rabies used either on its own or together with other cat vaccines, for primary and booster vaccination. The main measure of effectiveness was the ability of the vaccine to trigger immunity against rabies.

## What benefit has Purevax Rabies shown during the studies?

The laboratory studies showed that Purevax Rabies can give protection against rabies, and that the protection lasts for up to a year. The field trials showed that the vaccine is safe, and that it triggers a significant increase of anti-rabies antibodies. The vaccine can boost the immune response in cats that have received primary vaccination with another rabies vaccine.

## What is the risk associated with Purevax Rabies?

Occasionally, cats will develop temporary slight apathy (loss of interest in surroundings) and mild anorexia (loss of appetite) or 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 or oedema (swelling) which disappears within one or two weeks at most. For a full list of the side-effects reported with Purevax Rabies, see the package leaflet.

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

Canarypox recombinants such as those contained in Purevax Rabies are known to be safe for humans. Transient mild local or general adverse reactions related to the injection itself may be observed. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the doctor.

## Why has Purevax Rabies been approved?

The CVMP concluded that the benefits of Purevax Rabies outweigh the risks for the active immunisation of cats 12 weeks of age and older to prevent mortality due to rabies infection, and recommended that Purevax Rabies be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

## Other information about Purevax Rabies:

The European Commission granted a marketing authorisation valid throughout the European Union, for Purevax Rabies to MERIAL on 18.02.2011. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 18.02.2011.