

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

NETVAX

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 Netvax?

Netvax is a vaccine that contains a toxoid (a weakened toxin) from the bacterium *Clostridium perfringens* (*C. perfringens*) type A. The vaccine is an emulsion (a mixture of oil- and water-based liquids) for injection.

What is Netvax used for?

Netvax is used to vaccinate chickens against necrotic enteritis caused by *C. perfringens* type A, so that they pass their immunity against the disease on to their chicks. Necrotising enteritis is a disease that causes damage to the gut. Birds with the disease fail to thrive. Netvax is used to reduce the number of deaths, and the incidence and severity of the disease.

Netvax is given by injection into the breast muscle. The vaccination schedule consists of two doses: the first dose is given at 10 to 14 weeks of age, and then a second dose is given four to 10 weeks after the first. This second dose should be given at least six weeks before the hen will start to lay eggs. The hen can continue to pass on immunity to her chicks for almost a year after the end of vaccination.

How does Netvax work?

Netvax is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against diseases. Netvax contains small amounts of a toxoid from *C. perfringens* type A. When it is given to a chicken, its immune system recognises the toxoid as 'foreign' and makes antibodies against it. The antibodies are transferred from the chicken to the chicks via the eggs. These antibodies help the chicks to fight necrotic enteritis caused by *C. perfringens* type A if they are exposed to the bacterium after they have hatched.

Netvax contains one type of the toxoid from *C. perfringens* called the alpha toxoid. The vaccine also contains an 'adjuvant' (mineral oil) to stimulate a better response.

How has Netvax been studied?

The effectiveness of Netvax has been studied in several trials under laboratory and field conditions in chickens and their chicks. The main measure of effectiveness was the production of protective antibodies against *C. perfringens* type A in the chickens' blood and in their eggs. The studies compared chickens vaccinated with Netvax with birds that did not receive the vaccine. The studies also looked at death rates in the chicks hatched by vaccinated hens, and at the incidence and the severity of lesions caused by necrotic enteritis in the gut after the chicks were deliberately infected with the bacterium at three weeks of age.

What benefit has Netvax shown during the studies?

The studies showed that the vaccine is effective in stimulating the production of antibodies in chickens and in their eggs. The vaccine was well tolerated by the chickens, with no effect on the production of eggs or chicks.

In chicks hatched from vaccinated hens, the vaccine reduced the number of deaths, and the incidence and the severity of lesions caused by necrotic enteritis. The vaccine protected the chicks during the early period of life, when they are at greatest risk of the disease.

What is the risk associated with Netvax?

Vaccination causes swelling at the site of injection. Swelling after the first vaccination normally resolves within 30 days, and may last at least 35 days following the second vaccination.

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

This product contains mineral oil. Accidental injection of Netvax can cause severe pain and swelling, particularly if it is accidentally injected into a joint or finger. If accidental injection happens, seek prompt medical advice and show the package leaflet to the doctor. If pain persists for more than 12 hours after examination, seek medical advice again.

What is the time to allow before the animal can be slaughtered and the meat used for human consumption (withdrawal period)?

The withdrawal period is zero days.

Why has Netvax been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Netvax exceed the risks for the active immunisation of chickens, to provide passive immunisation against necrotic enteritis to their progeny, during the laying period, to reduce mortality and the incidence and severity of lesions caused by *C. perfringens* type A-induced necrotic enteritis. The CVMP recommended that Netvax should be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

Other information about Netvax:

The European Commission granted a marketing authorisation valid throughout the European Union for Netvax to Intervet International B.V. on 16 April 2009. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 16 April 2009.