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EPAR summary for the public

Suvaxyn PCV

Porcine circovirus recombinant virus (cpcv) 1-2, inactivated

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 Suvaxyn PCV?

Suvaxyn PCV is a vaccine that contains a recombinant (modified) porcine circovirus which has been inactivated (killed). Suvaxyn PCV is a suspension for injection.

What is Suvaxyn PCV used for?

Suvaxyn PCV is used to vaccinate pigs over the age of 3 weeks to reduce viral load in blood and lymphoid tissues and protect the pigs against the lesions in lymphoid tissues caused by Porcine Circovirus Type 2 as well as the reduced weight gain and potentially even death that is associated with Post-Weaning Multisystemic Wasting Syndrome (PMWS).

How does Suvaxyn PCV work?

Suvaxyn PCV is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Suvaxyn PCV contains small amounts of a form of the pig virus that has been modified to produce a protein from the form of the virus that causes disease, but killed so that it does not cause the disease and cannot spread. The vaccine also contains 'adjuvants' to stimulate a better response. When a pig is given the vaccine, the immune system recognises the killed viruses as 'foreign' and makes antibodies against them. In the future, the immune system will be able to recognise the protein from the disease-causing virus and produce antibodies more quickly when it is exposed to such viruses. This protects the pigs against the disease.

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How has Suvaxyn PCV been studied?

The effectiveness of Suvaxyn PCV has been studied in laboratory and field studies in a large number of pigs. These studies were well-designed to demonstrate the efficacy of the vaccine in the face of PMWS outbreaks: farms that were selected had a history of PMWS and the disease was confirmed to occur before starting of the respective studies, using internationally accepted standards.

What benefit has Suvaxyn PCV shown during the studies?

It has been demonstrated that the vaccine, when administered as recommended to piglets from 3 weeks of age induces active immunisation against Porcine Circovirus Type 2 (PCV2) and is able to reduce viral load in blood and lymphoid tissues, and the lesions in lymphoid tissues caused by porcine circovirus infection, as well as to reduce clinical signs –including loss of daily weight gain- and death associated with Post-Weaning Multisystemic Wasting Syndrome (PMWS).

What is the risk associated with Suvaxyn PCV?

The safety of the vaccine has been addressed in both laboratory and field conditions: a temporary increase in body temperature (up to 1.7°C) is very common during the first 24 hours after vaccination. Local tissue reactions in the form of swelling at the injection site are very common and may last for up to 26 days. The area of local tissue reactions is in general below 5 cm in diameter, but in some cases a larger swelling may occur. Immediate mild hypersensitivity-like reactions may occur commonly after vaccination (affecting up to 1 in 10 animals) resulting in short-lived clinical signs such as vomiting. These clinical signs normally resolve without treatment. Exceptionally, in some herds a large proportion of animals may react after vaccination. Severe anaphylactic (allergic) reactions are uncommon but may be lethal.

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

None.

What is the withdrawal period?

The withdrawal period is the time allowed after administration of the medicine and before the animal can be slaughtered and the meat used for human consumption. The withdrawal period for Suvaxyn PCV is zero days.

Why has Suvaxyn PCV been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Suvaxyn PCV exceed the risks for the approved indications and recommended that Suvaxyn PCV be given a marketing authorisation. The benefit/risk balance may be found in the scientific discussion module of this EPAR.

Other information about Suvaxyn PCV:

The European Commission granted a marketing authorisation valid throughout the European Union, for Suvaxyn PCV on 24 July 2009. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in October 2013.