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EPAR summary for the public

Suvaxyn CSF Marker

Classical swine fever vaccine (live recombinant)

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 Suvaxyn CSF Marker?

Suvaxyn CSF Marker is a recombinant veterinary vaccine that contains live bovine viral diarrhoea virus (BVDV) which has been modified to replace the envelope (E2) gene of BVDV with the corresponding gene of classical swine fever virus (CSFV). The vaccine is available as a lyophilisate (freeze dried powder) and solvent for injection.

What is Suvaxyn CSF Marker used for?

Suvaxyn CSF Marker is used to protect pigs against outbreaks of classical swine fever, a very severe and highly contagious viral disease of both wild and domestic pigs. This disease causes fever, skin lesions, convulsions and often leads to death of the animals.

The vaccine is given to pigs from seven weeks of age as a single injection into the muscle. Protection prevents mortality and reduces infection and disease. Protection starts two weeks after vaccination and lasts for at least six months.

The vaccine has potential marker properties which may allow detection of pigs infected with field CSFV as distinct from Suvaxyn CSF Marker vaccinated pigs, in accordance with the DIVA principle (differentiation of infection from vaccination).



How does Suvaxyn CSF Marker work?

Suvaxyn CSF Marker is a vaccine containing bovine viral diarrhoea virus, which can infect pigs but does not normally cause disease in them. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. The vaccine virus in Suvaxyn CSF Marker has been modified so that it will produce the E2 protein, which is part of the outer coat of the closely related virus CSFV, which it provides protection against. When the vaccine is given to a healthy pig, the animal's immune system recognises the vaccine virus as 'foreign' and makes antibodies against it. In the future, if the animals are exposed to CSFV, their immune system will be triggered by the virus and be able to respond more quickly. This will help to protect against the disease.

How has Suvaxyn CSF Marker been studied?

The effectiveness of the vaccine was first studied in a number of laboratory studies in pigs. The purpose of these studies was to establish how long it took for pigs to be fully protected and the length of time protection lasts against CSFV.

As CSF is a notifiable disease, it is not possible to conduct standard field studies. The effectiveness of Suvaxyn CSF Marker was further investigated in a small scale study with 30 eight-week-old piglets. Twenty piglets were given Suvaxyn CSF Marker and 10 piglets were given a placebo (dummy) injection. The main measure of effectiveness was development of antibodies against E2 protein 14 days after vaccination.

What benefit has Suvaxyn CSF Marker shown during the studies?

The laboratory studies showed that the vaccine had its full effect against CSFV by two weeks. Protection lasted at least six months after vaccination.

The field study showed that vaccination with Suvaxyn CSF Marker resulted in 19 out of 20 piglets developing antibodies against E2 protein.

What is the risk associated with Suvaxyn CSF Marker?

There are no known side effects with Suvaxyn CSF Marker when it is used according to the approved indication of the product information.

Suvaxyn CSF Marker should not be used to vaccinate sows. This is because if given to pregnant sows it does not prevent them from passing CSFV infection to their offspring but can hide signs of infection in the piglets, allowing them to spread the disease.

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 label shown to the doctor.

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 or eggs or milk used for human consumption. The withdrawal period for Suvaxyn CSF Marker for pigs is zero days.

Why has Suvaxyn CSF Marker been approved?

The CVMP concluded that the benefits of Suvaxyn CSF Marker exceed the risks for the approved indication and recommended that Suvaxyn CSF Marker be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Suvaxyn CSF Marker:

The European Commission granted a marketing authorisation valid throughout the European Union, for Suvaxyn CSF Marker on 10/02/2015. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in December 2014.