EMA/763051/2014
EMEA/V/C/002757

Suvaxyn CSF Marker *(classical swine fever vaccine (live recombinant))*

An overview of Suvaxyn CSF Marker and why it is authorised in the EU

What is Suvaxyn CSF Marker and what is it used for?

Suvaxyn CSF Marker is a veterinary vaccine used to protect pigs against outbreaks of classical swine fever (CSF), 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. It is also used to protect breeding sows in order to reduce infection of their unborn piglets by classical swine fever virus (CSFV).

Suvaxyn CSF Marker contains live bovine viral diarrhoea virus (BVDV) which has been modified to replace the envelope (E2) gene of BVDV with the corresponding gene of CSFV.

How is Suvaxyn CSF Marker used?

The vaccine is available as a lyophilisate (freeze dried powder) and solvent for injection; it is given to pigs from seven weeks of age as a single injection into the muscle. In young pigs, protection starts two weeks after vaccination and lasts for at least six months. In breeding sows, protection starts three weeks after vaccination.
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).

For more information about using Suvaxyn CSF Marker, see the package leaflet or contact your veterinarian or pharmacist.

How does Suvaxyn CSF Marker work?

Suvaxyn CSF Marker is a veterinary vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. The bovine 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 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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

be able to respond more quickly. This will help to protect against the disease.

What benefits of Suvaxyn CSF Marker have been shown in studies?

The effectiveness of the vaccine was studied in a number of laboratory studies to establish how long it took for pigs to be fully protected, the length of time protection lasts against CSFV, and whether, in pregnant sows, the virus was present in foetuses.

As CSF is a notifiable disease, it is not possible to conduct standard field studies. The effectiveness of Suvaxyn CSF Marker at protecting against CSFV was 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. 19 out of 20 piglets vaccinated with Suvaxyn CSF Marker developed antibodies against E2 protein. The vaccine had its full effect against CSFV by two weeks. Protection lasted for at least six months after vaccination.

In another study, a group of pregnant sows was given Suvaxyn CSF Marker and another group of sows was left unvaccinated to determine whether foetuses were protected against transplacental (through the placenta) CSFV transmission. After a challenge with a moderately virulent CSFV strain three weeks later, virus infection was not demonstrated in the vaccinated sows and their foetuses indicating protection against transplacental transmission, while the unvaccinated sows carried foetuses infected with CSFV. Only partial protection against transplacental viral transmission was observed when pregnant sows were challenged with a highly virulent CSFV strain two weeks after vaccination.

What are the risks associated with Suvaxyn CSF Marker?

In pregnant animals, a localised, small and transient swelling at the injection site was very common and lasted for up to 1 day. A small, transient increase in body temperature was observed commonly 4 hours after vaccination. This resolved spontaneously within 1 day after vaccination.
Transmission of the vaccine virus across the placenta, to the unborn piglets, has not been detected in the limited studies performed, but cannot be excluded.

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 required after administration of a medicine before the animal can be slaughtered and the meat used for human consumption. The withdrawal period for Suvaxyn CSF Marker for pigs is 'zero days', which means that there is no mandatory waiting time.

Why is Suvaxyn CSF Marker authorised in the EU?

The CVMP concluded that the benefits of Suvaxyn CSF Marker are greater than its risks and it can be authorised for use in the EU.

Other information about Suvaxyn CSF Marker

Suvaxyn CSF Marker received a marketing authorisation valid throughout the EU on 10/02/2015.

Further information on Suvaxyn CSF Marker can be found on the Agency's website: ema.europa.eu/en/medicines/veterinary/EPAR/suvaxyn-csf-marker

This overview was last updated in 11-2021.