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EPAR summary for the public

ERYSENG PARVO

Porcine parvovirosis and swine erysipelas vaccine (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 Eryseng Parvo?

Eryseng Parvo is a veterinary vaccine that contains inactivated (killed) porcine parvovirus and *Erysipelothrix rhusiopathiae* bacteria. It contains a strain of porcine parvovirus called NADL-2 and a strain of *Erysipelothrix rhusiopathiae* called R32E11. Eryseng Parvo is available as a suspension for injection.

What is Eryseng Parvo used for?

Eryseng Parvo is used to protect embryonic and foetal (unborn) piglets against porcine parvovirus infection via the placenta. Porcine parvovirus causes infertility, still births and small litters in sows (female pigs that have had piglets). Eryseng Parvo is also used to protect male and female pigs against swine erysipelas caused by *Erysipelothrix rhusiopathiae*, serotype 1 and serotype 2. Swine erysipelas is a bacterial disease of pigs characterised by sudden death, fever associated with diamond skin lesions, arthritis and by abortion in pregnant sows.

The vaccine is given to pigs from six months of age as an injection into the neck muscles, repeated after three to four weeks. A single injection is given two to three weeks before each mating so approximately every six months.

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How does Eryseng Parvo work?

Eryseng Parvo is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. When Eryseng Parvo is given to pigs the animals' immune system recognises the virus and bacteria as 'foreign' and makes antibodies against them. In the future, if the animals are exposed to porcine parvovirus and *Erysipelothrix rhusiopathiae* bacteria, the immune system will be able to respond more quickly. This will help protect them against porcine parvovirus and swine erysipelas.

Eryseng Parvo contains an adjuvant (aluminium hydroxide, DEAE-dextran and ginseng) to enhance the immune response.

How has Eryseng Parvo been studied?

For porcine parvovirus a laboratory study was conducted involving three groups of 11 gilts (female pigs that have not yet had piglets) vaccinated with different concentrations of porcine parvovirus. Pigs were vaccinated with two doses at an interval of three weeks, with the second dose given three to four weeks before mating. There was also an unvaccinated control group. Pigs were challenged with parvovirus at day 40 of pregnancy and then euthanized (humanely killed) at day 90 of pregnancy. The measure of effectiveness was absence of porcine parvovirus and anti-porcine parvovirus antibodies in the foetuses.

For swine erysipelas two laboratory studies were conducted. The first study involved 40 pigs; 30 pigs were vaccinated with two doses, separated by three weeks, while a control group of 10 pigs received placebo (dummy treatment). All pigs were challenged 22 days after the second vaccination dose with injections of the bacteria *Erysipelothrix rhusiopathiae* serotypes 1 and 2. The measure of effectiveness was the percentage of vaccinated pigs free from specific (diamond shaped) skin lesions at the challenge site. The second laboratory study involved 15 gilts which were vaccinated according to the basic vaccination schedule with a booster dose six months later. The pigs were challenged a further six months later with injections of the bacteria *Erysipelothrix rhusiopathiae* serotypes 1 and 2 and the measure of effectiveness was the percentage of pigs protected by vaccination.

What benefit has Eryseng Parvo shown during the studies?

The parvovirus study showed that Eryseng Parvo protected 100% of the foetuses whilst 89% of foetuses were mummified in the control group.

For swine erysipelas, the first laboratory study showed that 90% (27 out of 30) of vaccinated pigs were protected against *Erysipelothrix rhusiopathiae* serotype 1 remaining free of specific skin lesions whilst 93% (28 out of 30) of vaccinated pigs were protected against *Erysipelothrix rhusiopathiae* serotype 2 remaining free of specific skin lesions. The onset of immunity was shown to be three weeks. The second laboratory study showed 93% (14 out of 15) pigs were protected against challenge with *Erysipelothrix rhusiopathiae* serotypes 1 and 2. The duration of protection was confirmed to be six months.

What is the risk associated with Eryseng Parvo?

The most common side effect (seen in more than 1 in 10 pigs) with Eryseng Parvo is mild to moderate inflammation at the injection site which typically resolves within four days but in some cases may persist for up to 12 days post-vaccination.

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. The withdrawal period for Eryseng Parvo is zero days.

Why has Eryseng Parvo been approved?

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

Other information about Eryseng Parvo:

The European Commission granted a marketing authorisation valid throughout the European Union, for Eryseng Parvo on 8 July 2014. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in May 2014.