EMA/279182/2014
EMEA/V/C/002761

EPAR summary for the public

ERYSENG

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?

Eryseng is a veterinary vaccine that contains inactivated (killed) *Erysipelothrix rhusiopathiae* bacteria. It contains a bacterial strain called R32E11. Eryseng is available as a suspension for injection.

What is Eryseng used for?

Eryseng is used to protect male and female pigs against swine erysipelas caused by *Erysipelothrix rhusiopathiae* bacteria of specific types called 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.

How does Eryseng work?

Eryseng is a bacterial vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. When Eryseng is given to pigs the animals' immune system recognises the bacteria as 'foreign' and makes antibodies against them. In the future, if the

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

animals are exposed to *Erysipelothrix rhusiopathiae* bacteria, the immune system will be able to respond more quickly. This will help protect them against swine erysipelas.

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

How has Eryseng been studied?

In a laboratory study involving 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.

A second laboratory study involved 15 gilts (female pigs that have not yet had piglets) 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 shown during the studies?

The first laboratory study showed 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. In the control group more than 80% of pigs showed specific skin lesions. The onset of immunity was shown to be three weeks.

The second laboratory study showed 93% (14 out of 15) of 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?

The most common side effect (seen in more than 1 in 10 pigs) with Eryseng 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 is zero days.

Why has Eryseng been approved?

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

Other information about Eryseng:

The European Commission granted a marketing authorisation valid throughout the European Union, for Eryseng on 4 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.