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EPAR summary for the public

Coxevac

Inactivated *Coxiella burnetii* vaccine

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 Coxevac?

Coxevac is a veterinary vaccine that contains inactivated (killed) *Coxiella burnetii* bacteria. Coxevac is available as a suspension for injection.

What is Coxevac used for?

Coxevac is used in cattle to lower the risk of spreading *Coxiella burnetii* infection and in goats to reduce abortions caused by the infection as well as reduce spreading the infection. *Coxiella burnetii* is a bacterium that affects animals, including cattle and goats, and man. The disease it causes is known as Q-fever. In cattle and goats Q-fever can cause abortions, still births and pneumonia. The vaccine is given to cattle and goats from three months of age. The vaccine is given as two injections under the skin, three weeks apart. Nine months later, two additional injections should be given to cattle, again three weeks apart. For goats, one injection should be given one year later.

How does Coxevac work?

Coxevac is a bacterial vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. When Coxevac is given to cattle and goats, their immune system recognises the bacteria contained in the vaccine as 'foreign' and makes antibodies to defend against them. In the future, if the animals are exposed to *Coxiella burnetii* bacteria, the immune system will be able to respond more quickly. This will help to protect against the disease.

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This is of particular importance because *Coxiella burnetii* can lead to a disease in humans called Q-fever and decreasing the disease in animals will decrease the likelihood of transmitting the disease to humans.

How has Coxevac been studied?

The effectiveness of Coxevac was investigated in both laboratory and field studies.

A field study determined the effectiveness of the vaccine in cattle that came from farms where *Coxiella burnetii* was present. The effectiveness of the vaccine in goats has been determined in two field studies with pregnant goats exposed to *Coxiella burnettii*.

What benefit has Coxevac shown during the studies?

The studies conducted in cattle and goats showed that Coxevac reduces bacteria shedding (which is a major factor in spreading the disease) in vaginal discharge and milk, whilst in goats Coxevac reduced bacteria shedding in faeces and the placenta as well. The studies in goats also showed a lower proportion of abortions in the goats that were vaccinated compared with unvaccinated goats.

The duration of protection was established to be 280 days in cattle and one year in goats.

What is the risk associated with Coxevac?

In cattle it is very common to see a swelling of maximum diameter of 9 to 10 cm at the injection site, which may last for 17 days. The reaction gradually reduces and disappears without need for treatment.

In goats it is very common to see a palpable reaction of 3 to 4 cm diameter at the injection site which may last for 6 days. The reaction reduces and disappears without need for treatment. In goats it is also very common to observe a slight increase of rectal temperature for 4 days post-vaccination without other general signs.

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

In the case of accidental self-injection, medical advice should be sought immediately and the package leaflet or the label shown to the doctor.

What is the withdrawal period?

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

Why has Coxevac been approved?

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

Coxevac was initially authorised under ‘exceptional circumstances’. This means that it was not possible to obtain complete information about Coxevac at the time of the initial authorisation. The European Medicines Agency (EMA) reviewed additional information according to an agreed timetable on the

efficacy of the vaccine. In 2014 the CVMP considered that the submitted data were adequate for the authorisation of Coxevac to convert to a normal status.

Other information about Coxevac:

The European Commission granted a marketing authorisation valid throughout the European Union, for Coxevac on 30 September 2010. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in November 2014.