Circovac
porcine circovirus type 2 vaccine (inactivated)

This is a summary of the European public assessment report (EPAR) for Circovac. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use Circovac.

For practical information about using Circovac, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is Circovac and what is it used for?

Circovac is a vaccine used to protect pigs against porcine circovirus type 2 (PCV2). Circovac is used to reduce the changes in and damage to lymphoid tissues (cells and tissues that make up the lymphatic system, such as lymph nodes) associated with PCV2 infection in piglets and to help reduce the risk of dying from this infection. PCV2 infections can produce clinical signs such as weight loss or failure to grow, enlarged lymph nodes, difficulty breathing, pale skin and jaundice (yellowing of the skin). Circovac contains an inactivated (killed) porcine circovirus type 2 (PCV2) strain.

How is Circovac used?

Circovac is available as an emulsion for injection and can only be obtained with a prescription. The vaccine is given to female pigs before and/or during pregnancy. Their piglets then obtain temporary protection against PCV2 when they drink the colostrum (first milk) from their vaccinated mothers. This is called ‘passive immunisation’. In this case, the effect of the vaccine lasts for up to 5 weeks.

Circovac can also be given directly to piglets from three weeks of age (active immunisation). In this case, the effect of the vaccine lasts for at least 14 weeks. Circovac is given by injection into a muscle. For the initial vaccination the number of injections needed and the dose varies according to the type of female pig being treated: gilts (female pigs that have not yet had piglets) should receive one 2 ml injection three times; sows (female pigs that have had piglets before) should receive one 2 ml injection twice. The timing of the injection is adjusted according to the dates of mating and farrowing (giving birth). In all cases the last dose is given at least two weeks before the expected date of farrowing.
Sows should be revaccinated at each pregnancy with one injection two to four weeks before farrowing. Piglets should be vaccinated with one 0.5 ml injection once.

**How does Circovac work?**

Porcine circovirus type 2 (PCV2) is known to infect, and cause a wide variety of clinical signs and syndromes in pigs. The infection of piglets occurs mostly during the first 6 weeks of life, when the immune system of piglets is still maturing. Symptoms include weight loss (or failure to grow), enlarged lymph nodes, difficulties in breathing, and, less commonly, diarrhoea, pale skin and jaundice (yellowing of the skin).

Circovac is a vaccine. Vaccines work by ‘teaching’ the immune system (the body’s natural defences) how to defend itself against a disease. Circovac contains PCV2 strain that has been inactivated so it cannot cause the disease. When it is given directly to pigs, the immune system of the animal recognises the virus as ‘foreign’ and makes antibodies against it. In the future, if the animals are exposed to PCV2, the immune system will be able to produce antibodies more quickly. This will help protect them against the disease. When given to the mother, her antibodies are transferred to the piglets through the colostrum and provide temporary protection.

Before use, the vaccine is made up by mixing together a suspension that contains the virus particles with an emulsion. The resulting emulsion is then injected. The emulsion contains an ‘adjuvant’ (a compound containing oil) to enhance the immune response.

**What benefits of Circovac have been shown in studies?**

Laboratory and field studies have been conducted with Circovac in pregnant pigs and piglets of various breeds. The studies showed that vaccination of the mothers with Circovac can reduce the incidence of damage associated with PCV2 infection in the lymphoid tissues of their piglets. Although the outcome of some of the studies was partially compromised by the complex nature of PCV2 infections, the large number of pigs involved (from 63 farms) and the variety of experimental and clinical conditions showed a reduction in the overall death rates of piglets related to PCV2 infections of between 3.6% and 10%.

**What are the risks associated with Circovac?**

Circovac can cause a temporary redness or swelling at or around the injection site, which can last for up to four days after the injection. Following injection, pigs may have an increased rectal temperature of about 1.4 °C for up to two days, and in some pigs of up to 2.5 °C, but this should not last more than 24 hours after the injection. Other rarer side effects in the injected pigs are reduced activity and food intake, but these are also temporary. For a full list of all side effects reported with Circovac, see the package leaflet.

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

Circovac contains mineral oil. Accidental injection may cause severe pain and swelling, particularly if injected into a joint or finger – this could result in the loss of the finger if prompt medical attention is not given. If someone is accidentally injected with this product, they must seek medical advice immediately even if only a very small amount is injected. The package leaflet should be shown to the doctor. If pain persists for more than 12 hours after medical examination, the doctor should be contacted again.
What is the withdrawal period in food-producing animals?

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 meat from pigs treated with Circovac is zero days, which means that there is no mandatory waiting time.

Why is Circovac approved?

The Agency’s Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Circovac’s benefits are greater than its risks and recommended that it be approved for use in the EU.

Other information about Circovac

The European Commission granted a marketing authorisation valid throughout the EU for Circovac on 21 June 2007.

The full EPAR for Circovac can be found on the Agency’s website: ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports. For more information about treatment with Circovac animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in May 2017.