



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/464279/2015  
EMA/V/C/003942

## EPAR summary for the public

---

# Porcilis PCV ID

## Porcine circovirus vaccine (inactivated)

This is a summary of the European public assessment report (EPAR) for Porcilis PCV ID. 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 Porcilis PCV ID.

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

### What is Porcilis PCV ID and what is it used for?

Porcilis PCV ID is a veterinary vaccine against porcine circovirus type 2 (PCV2) infection in pigs. The vaccine is used to reduce viraemia (presence of the virus in the blood), virus load in the lungs and lymphoid tissues and virus shedding. The vaccine is also used to reduce loss of daily weight gain and mortality associated with PV2 infection. PCV2 infection is widespread and nearly all pig herds are infected with PCV2. PCV2 is recognised as the primary cause of post-weaning multisystemic wasting syndrome (PMWS), but is also associated with a number of other conditions collectively known as porcine circovirus disease in Europe (PCVD) e.g porcine respiratory disease complex (PRDC), enteritis, reproductive disorders. PCVDs are considered to have a severe impact on pig production.

Porcilis PCV ID contains the active substance porcine circovirus (PCV2) ORF2 subunit antigen.

### How is Porcilis PCV ID used?

Porcilis PCV ID is available as an emulsion for injection and can only be obtained with a prescription. The vaccine is given to fattening pigs from three weeks of age as a single injection into the skin at the side of the neck, along the back or in the hind leg. Protection against PCV 2 starts two weeks after vaccination and lasts for 23 weeks after vaccination. The vaccine is given using a suitable needle-free device for injection into the skin.

For further information, see the package leaflet.



## **How does Porcilis PCV ID work?**

Porcilis PCV ID is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. The vaccine contains small amounts of a protein from PCV2. The vaccine does not contain any live PCV2 so that it cannot cause disease. When Porcilis PCV ID is given to pigs, the animals' immune system recognises the virus protein as 'foreign' and reacts by building up an active immune response. In the future, if the animals are exposed to the virus the immune system will be able to respond more quickly. This will help reduce the PCV2 viraemia, virus load in the lungs and lymphoid tissue and virus shedding. It will also help to reduce the loss of daily weight gain and mortality associated with PCV2 infection.

Porcilis PCV ID contains the adjuvant light mineral oil and dl- $\alpha$ -tocopheryl acetate to enhance the immune response.

## **What benefits of Porcilis PCV ID have been shown in studies?**

The vaccine was first studied in a number of laboratory studies in pigs. The laboratory studies showed that the vaccine had its full effect against PCV2 by two weeks and that protection lasted 23 weeks after vaccination.

Porcilis PCV ID has also been investigated in three field studies involving pig farms where PCV2 infection was present. The main measures of effectiveness were average daily weight gain in the finishing period (fattening pigs in the period prior to slaughter) and PCV2 viraemia (virus in the blood). In all three studies average daily weight gain in the finishing period was significantly higher in the pigs vaccinated with Porcilis PCV ID compared with the non-vaccinated pigs. Similarly PCV2 viraemia was significantly lower in the vaccinated pigs compared with non-vaccinated pigs.

## **What are the risks associated with Porcilis PCV ID?**

The most common side effect with Porcilis PCV ID (seen in more than 1 in 10 pigs) is a short-lived local reaction with hard non-painful swellings up to 2 cm in diameter which disappear within about five weeks of vaccination.

For the full list of restrictions, see the package leaflet.

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

Safety information has been included in the summary of product characteristics and the package leaflet for Porcilis PCV ID, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

Porcilis PCV ID is an emulsion containing 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 attention 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, the doctor should be consulted again.

## **What is the withdrawal period in food-producing animals?**

The withdrawal period is the time required after administration of a medicine before an animal can be slaughtered and the meat used for human consumption.

The withdrawal period for meat from pigs treated with Porcilis PCV ID is 'zero' days, which means that there is no mandatory waiting time.

### **Why is Porcilis PCV ID approved?**

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

### **Other information about Porcilis PCV ID**

The European Commission granted a marketing authorisation valid throughout the EU for Porcilis PCV ID on 28 August 2015.

The full EPAR for Porcilis PCV ID can be found on the Agency's website: [ema.europa.eu/Find/medicine/Veterinary medicines/European public assessment reports](http://ema.europa.eu/Find/medicine/Veterinary%20medicines/European%20public%20assessment%20reports). For more information about treatment with Porcilis PCV ID, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in July 2015.