Porcilis PCV M Hyo
Porcine circovirus and *Mycoplasma hyopneumoniae* vaccine (inactivated)

This 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 Porcilis PCV M Hyo?**

Porcilis PCV M Hyo is a veterinary vaccine that contains porcine circovirus type 2 (PCV2) subunit antigen and an inactivated (killed) strain of *Mycoplasma hyopneumoniae* bacteria. Porcilis PCV M Hyo is available as an emulsion for injection.

**What is Porcilis PCV M Hyo used for?**

Porcilis PCV M Hyo is used to protect pigs against two separate infections, porcine circovirus and *Mycoplasma hyopneumoniae*.

- Porcine circovirus type 2 (PCV2) infections can produce clinical signs such as weight loss or failure to grow, enlarged lymph nodes, difficulty in breathing, diarrhoea, pale skin and jaundice (yellowing of the skin).
- Infection with the bacterium *Mycoplasma hyopneumoniae* in pigs causes a disease of the airways called enzootic pneumonia. Affected pigs often have a cough and fail to thrive.

The vaccine is given to pigs from three weeks of age as a single injection into the neck muscle. Protection against PCV2 starts at two weeks after vaccination and for *Mycoplasma hyopneumoniae* it starts four weeks after vaccination. Protection lasts for 22 weeks after vaccination for PCV2 and for 21 weeks after vaccination for *Mycoplasma hyopneumoniae*. 
How does Porcilis PCV M Hyo work?

Porcilis PCV M Hyo 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 and whole *Mycoplasma hyopneumoniae* bacteria that have been killed (inactivated) so that they do not cause disease. When Porcilis PCV M Hyo is given to pigs the animals’ immune system recognises the virus protein and bacteria as ‘foreign’ and makes antibodies against them. In the future, if the animals are exposed to the virus or the bacteria the immune system will be able to respond more quickly. This will help protect the pigs against porcine circovirus and *Mycoplasma hyopneumoniae* infections.

Porcilis PCV M Hyo contains the adjuvants light mineral oil and aluminium hydroxide to enhance the immune response.

How has Porcilis PCV M Hyo been studied?

The effectiveness of the vaccine was first studied in a number of laboratory studies in pigs. The purpose of these studies was to establish how long it took for pigs to be fully protected and the length of time protection lasts against PCV2 and *Mycoplasma hyopneumoniae*.

The effectiveness of Porcilis PCV M Hyo was investigated in 10 field studies involving pig farms where signs of PCV2 and/or *Mycoplasma hyponeumoniae* infections had been detected. In each study around 300 suckling piglets were vaccinated with Porcilis PCV M Hyo and a second group of around 300 suckling piglets received a dummy injection. The main measures of effectiveness were average daily weight gain during the finishing period, the level of PCV2 in the blood and a score for the severity of damage (lesions) to the lung.

What benefit has Porcilis PCV M Hyo shown during the studies?

The laboratory studies showed that the vaccine had its full effect against PCV2 by two weeks and against *Mycoplasma hyopneumoniae* by four weeks. Protection lasted 22 weeks after vaccination for PCV2 and 21 weeks after vaccination for *Mycoplasma hyopneumoniae*.

The field studies showed that vaccination with Porcilis PCV M Hyo reduced PCV2 levels in the blood and the severity of lung lesions caused by *Mycoplasma hyopneumoniae* and the loss of daily weight gain during the finishing period (the fattening period prior to slaughter).

What is the risk associated with Porcilis PCV M Hyo?

The most common side effect (seen in more than 1 in 10 pigs) with Porcilis PCV M Hyo is a short lived increase in body temperature of up to 2 °C on the day of vaccination.

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

Porcilis PCV M Hyo 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 after medical examination, the doctor should be contacted again.
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 Porcilis PCV M Hyo is zero days.

Why has Porcilis PCV M Hyo been approved?

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

Other information about Porcilis PCV M Hyo:

The European Commission granted a marketing authorisation valid throughout the European Union, for Porcilis PCV M Hyo on 7 November 2014. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in September 2014.