EMA/546649/2014
EMEA/V/C/003796

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

An overview of Porcilis PCV M Hyo and why it is authorised in the EU

## What is Porcilis PCV M Hyo and what is it used for?

Porcilis PCV M Hyo is a veterinary vaccine used to protect pigs against two separate infections, caused by 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.

Porcilis PCV M Hyo contains porcine circovirus type 2 (PCV2) subunit antigen (a protein derived from part of the virus) and an inactivated (killed) strain of *Mycoplasma hyopneumoniae* bacteria.

## How is Porcilis PCV M Hyo used?

Porcilis PCV M Hyo is available as an injection and can only be obtained with a prescription.

The vaccine is given to pigs from three days of age as two injections into the neck muscle at least 18 days apart, or from three weeks of age as a single injection into the neck muscle. The two-dose vaccination schedule is recommended when PCV2 and/or *Mycoplasma hyopneumoniae* infections occur early.

With two-dose vaccination, protection against PCV2 starts at 18 days after the first injection and for *Mycoplasma hyopneumoniae* it starts 3 weeks after the second injection. With single-dose vaccination, protection against PCV2 starts at two weeks after the injection and for *Mycoplasma hyopneumoniae* it starts four weeks after the injection. For both vaccination schedules protection lasts for 22 weeks after (the last) injection for PCV2 and for 21 weeks after (the last) injection for *Mycoplasma hyopneumoniae*.

For more information about using Porcilis PCV M Hyo, see the package leaflet or contact your veterinarian or pharmacist.

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

## 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.

## What benefits of Porcilis PCV M Hyo have been shown in studies?

Laboratory studies in pigs showed that with two-dose vaccination the vaccine had its full effect against PCV2 by 18 days after first injection and against *Mycoplasma hyopneumoniae* by three weeks after the second injection, whilst with single-dose vaccination the vaccine had its full effect against PCV2 by two weeks and against *Mycoplasma hyopneumoniae* by four weeks. With both vaccination schedules protection lasted 22 weeks after (the last) injection for PCV2 and 21 weeks after (the last) injection for *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 hyopneumoniae* infections had been detected. In each study around 300 suckling piglets were vaccinated once with Porcilis PCV M Hyo and a second similar-sized group of piglets received a dummy injection. In three of the studies there was a third similar-sized group of pigs that were vaccinated using the two-dose schedule. The field studies showed that both single and repeated vaccination with Porcilis PCV M Hyo reduced PCV2 levels in the blood and the severity of lung damage (lesions) caused by *Mycoplasma hyopneumoniae* as well as the loss of daily weight gain during the finishing period (the fattening period prior to slaughter). The repeated dose vaccination often gave slightly better results than the single vaccination.

## What are the risks 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 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 Porcilis PCV M Hyo is zero days.

## Why is Porcilis PCV M Hyo authorised in the EU?

The European Medicines Agency decided that Porcilis PCV M Hyo's benefits are greater than its risks and it can be authorised for use in the EU. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

## Other information about Porcilis PCV M Hyo

Porcilis PCV M Hyo received a marketing authorisation valid throughout the EU for Porcilis PCV M Hyo on 7 November 2014.

Further information on Porcilis PCV M Hyo can be found on the Agency's website: ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports.

This overview was last updated in May 2018.