



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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CircoMax Myco (*porcine circovirus vaccine (inactivated, recombinant) and Mycoplasma hyopneumoniae (inactivated) vaccine*)

An overview of CircoMax Myco and why it is authorised in the EU

What is CircoMax Myco and what is it used for?

CircoMax Myco is a veterinary vaccine used to protect pigs against two separate infections caused by porcine circovirus type 2 (PCV2) and *Mycoplasma hyopneumoniae*.

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 *M. hyopneumoniae* in pigs causes a disease of the airways called enzootic pneumonia. Affected pigs often have a cough and fail to thrive.

CircoMax Myco contains inactivated (killed) recombinant porcine circovirus and an inactivated strain of *M. hyopneumoniae*.

How is CircoMax Myco used?

The vaccine is given to pigs from three weeks of age as a single 2 ml intramuscular injection in the neck behind the ear. The vaccine can be also given to pigs from three days of age as a split dose vaccination consisting of two 1 ml-injections, given approximately 3 weeks apart.

Protection starts three weeks after the last injection for both vaccination schedules (either single or split) and lasts for 23 weeks.

The medicine can only be obtained with a prescription. For further information, see the package leaflet or contact your veterinarian or pharmacist.

How does CircoMax Myco work?

CircoMax Myco is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. When CircoMax Myco is given to pigs, the animals' immune system recognises the virus and bacteria in the vaccine 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 *M. hyopneumoniae* infections.

What benefits of CircoMax Myco have been shown in studies?

Laboratory studies in pigs showed that the vaccine had its full effect three weeks after the last vaccination for both vaccination schedules (either single or split), and that protection lasted 23 weeks after vaccination.

To test whether maternally derived antibodies (MDA), which are passed to the piglets via the colostrum (first milk), could influence the response of the piglets to the vaccine, three studies were performed in MDA-positive piglets to assess the efficacy of the PCV2a component of CircoMax Myco, an additional three studies for the PCV2b component, and two studies for the *M. hyopneumoniae* component. These studies showed that the split dose vaccination scheme provides notably better protection against PCV2 infection than the single dose scheme in the presence of MDAs. No detrimental effect of MDAs on the efficacy of the *M. hyopneumoniae* component of CircoMax Myco were observed in relevant studies.

In order to assess the efficacy of CircoMax Myco in field conditions, six studies were conducted in two different EU countries involving 3-day-old pigs (split dose: 3 studies) and 3-week-old pigs (single dose: 3 studies). The field studies generally supported the claims of protection against PCV2a and PCV2b, and partly supported the claim for protection against *M. hyopneumoniae*. Cross-protection against PCV2d was demonstrated in three studies conducted in the United States. The field studies provided evidence on reduction of the disease-induced losses of body weight.

What are the risks associated with CircoMax Myco?

The most common side effects with CircoMax Myco (which may affect more than 1 in 10 animals) are a transient increase in body temperature, not exceeding 2.1°C that resolves spontaneously within 24 hours without treatment and mild inflammation at the site of injection.

For the full list of side effects of CircoMax Myco, 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 CircoMax Myco, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

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 vaccinated with CircoMax Myco is 'zero' days, which means there is no mandatory waiting time.

Why is CircoMax Myco approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that CircoMax

Myco's benefits are greater than its risks and recommended that it be approved for use in the EU.

Other information about CircoMax Myco?

CircoMax Myco received a marketing authorisation valid throughout the EU on 09/12/2020.

Further information on CircoMax Myco can be found on the Agency's website:

www.ema.europa.eu/en/medicines/veterinary/EPAR/circomax-myco

This overview was last updated in 10-2021.