



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/601217/2015
EMA/V/C/003924

EPAR summary for the public

Suvaxyn Circo+MH RTU

porcine circovirus and porcine enzootic pneumonia vaccine (inactivated)

This is a summary of the European public assessment report (EPAR) for Suvaxyn Circo+MH RTU. 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 Suvaxyn Circo+MH RTU.

For practical information about using Suvaxyn Circo+MH RTU, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is Suvaxyn Circo+MH RTU and what is it used for?

Suvaxyn Circo+MH RTU is a veterinary vaccine used to protect pigs over the age of 3 weeks against infections with porcine circovirus and the bacteria *Mycoplasma hyopneumoniae*.

Porcine circovirus type 2 (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).

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

Suvaxyn Circo+MH RTU contains inactivated (killed) active substances derived from porcine circovirus type 2 and *Mycoplasma hyopneumoniae* bacteria.

How is Suvaxyn Circo+MH RTU used?

Suvaxyn Circo+MH RTU, which is available as a liquid for injection, is given to pigs from three weeks of age as a single injection into the muscle in the neck behind the ear. Protection starts three weeks after vaccination and lasts for 23 weeks after vaccination. Suvaxyn Circo+MH RTU is only available on prescription.

For further information, see the package leaflet.



How does Suvaxyn Circo+MH RTU work?

Suvaxyn Circo+MH RTU 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 Suvaxyn Circo+MH RTU is given to pigs the animals' immune system recognises the viral 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.

Suvaxyn Circo+MH RTU also contains adjuvants (ingredients that strengthen the immune response) called squalene, poloxamer 401 and polysorbate 80.

What benefits of Suvaxyn Circo+MH RTU have been shown in studies?

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 pigs to be fully protected and how long the protection against PCV2 and *Mycoplasma hyopneumonia* lasted. The studies showed that the vaccine had its full effect against PCV2 and *Mycoplasma hyopneumonia* by three weeks after vaccination. Protection lasted 23 weeks after vaccination for PCV2 and *Mycoplasma hyopneumonia*.

The effectiveness of Suvaxyn Circo+MH RTU against PCV2 infection was also studied in three field studies. The field studies showed that Suvaxyn Circo+MH RTU reduced the PCV2 viraemia (presence of virus in the blood) compared to pigs given dummy vaccination.

What are the risks associated with Suvaxyn Circo+MH RTU?

The most common side effect with Suvaxyn Circo+MH RTU (which may affect more than 1 in 10 pigs) are an increase in body temperature (on average 1 °C) in the first 24 hours after vaccination which resolves within 48 hours without treatment. Swelling, less than 2 cm in diameter, heat, redness at the injection site and pain to the touch which may last up to 2 days were also seen.

For the full list of all side effects reported with Suvaxyn Circo+MH RTU, see the package leaflet.

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

None.

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 Suvaxyn Circo+MH RTU for is 'zero' days, which means there is no mandatory waiting time.

Why is Suvaxyn Circo+MH RTU approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Suvaxyn Circo+MH RTU's benefits are greater than its risks and recommended that it be approved for use in the EU.

Other information about Suvaxyn Circo+MH RTU?

The European Commission granted a marketing authorisation valid throughout the EU for Suvaxyn Circo+MH RTU on 6 November 2015.

The full EPAR for Suvaxyn Circo+MH RTU 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 Suvaxyn Circo+MH RTU, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in April 2017.