



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/363425/2020  
EMA/V/C/005272

## Mhyosphere PCV ID (*Mycoplasma hyopneumoniae* and Porcine circovirus (inactivated, recombinant))

An overview of Mhyosphere PCV ID and why it is authorised in the EU

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

Mhyosphere PCV ID is a veterinary vaccine used to protect pigs against two swine pathogens, *Mycoplasma hyopneumoniae* and Porcine circovirus, at the same time.

Mhyosphere PCV ID consists of the inactivated recombinant *M. hyopneumoniae*<sup>cpPCV2</sup>, strain Nexhyon, expressing the Porcine circovirus type 2 (PCV2) capsid protein.

- 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.
- 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).

### How is Mhyosphere PCV ID used?

The vaccine is given to pigs from three weeks of age onwards as a single intradermal administration at the sides of the neck using a suitable needle-free device able to administer 0.2 ml doses per shot.

Protection against *M. hyopneumoniae* starts 3 weeks after vaccination and lasts for 23 weeks. Protection against PCV2 starts two weeks after vaccination and lasts for 22 weeks.

The medicine can only be obtained with a prescription.

For more information about using Mhyosphere PCV ID, see the package leaflet or contact your veterinarian or pharmacist.

### How does Mhyosphere PCV ID work?

Mhyosphere 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 *M. hyopneumoniae* with the integrated capsid protein from PCV2 that have been killed (inactivated) so that they do not cause disease. When Mhyosphere PCV ID is given to pigs, the animals' immune system recognises the bacteria and virus proteins as 'foreign' and makes antibodies against them. In

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the future, if the animals are exposed to the bacteria or the virus the immune system will be able to respond more quickly. This will help protect the pigs against *M. hyopneumoniae* and porcine circovirus related diseases.

Mhyosphere PCV ID contains the adjuvant light mineral oil to enhance the immune response.

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

Laboratory studies in pigs showed that the vaccine had its full effect against *M. hyopneumoniae* by three weeks and against PCV2 by two weeks. Protection lasted 23 weeks after vaccination for *Mycoplasma hyopneumoniae* and 22 weeks after vaccination for PCV2.

The effectiveness of Mhyosphere PCV ID was investigated in one field study involving seven commercial fattening pig farms in two EU countries where signs of *M. hyopneumoniae* and/or PCV2 infections had been recently confirmed. In the study, 2,507 piglets were enrolled and around half were vaccinated with Mhyosphere PCV ID and a second similar-sized group of piglets received a placebo (a dummy injection). The field studies showed that a single vaccination with Mhyosphere PCV ID reduced the incidence of lung lesions associated with porcine enzootic pneumonia caused by *M. hyopneumoniae* in 3-week-old piglets for fattening and reduced viraemia, the percentage of viraemic pigs, PCV2 nasal and faecal shedding and the percentage of PCV2 shedder pigs (nasal and faecal) associated with PCV2 related diseases as observed under field conditions. In addition, Mhyosphere PCV ID reduced the culling rate and the loss of daily weight gain caused by *M. hyopneumoniae* and/or PCV2 related diseases at 6 months of age as observed in field trials.

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

The most common side effects with Mhyosphere PCV ID (which may affect more than 1 in 10 animals) are mild transient local reactions consisting of non-painful skin inflammations, of less than 3 cm in diameter.

Other common side effects with Mhyosphere PCV ID (which may affect up to 1 in 10 animals) are moderate inflammations (between 3-5 cm) at day 1 post-vaccination, which generally decrease to less than 3 cm the next day. These local reactions can be observed during the first week after vaccination and last for 1 to 3 days. One or two weeks later, these local reactions can reappear lasting for 1 to 7 days. Local reactions disappear completely within approximately 3 weeks after vaccination without treatment. A slight transient increase in body temperature (mean 0.3 °C, in individual pigs less than 1.5 °C) is a common side effect (which may affect up to 1 in 10 animals). This slight increase subsided spontaneously within 48 hours without treatment.

### **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 Mhyosphere PCV ID, including the appropriate precautions to be followed by healthcare professionals.

Mhyosphere 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 after medical examination, the doctor should be contacted 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 Mhyosphere PCV ID is zero days.

## **Why is Mhyosphere PCV ID authorised in the EU?**

The European Medicines Agency decided that Mhyosphere PCV ID's benefits are greater than its risks and it can be authorised for use in the EU.

## **Other information about Mhyosphere PCV ID**

Mhyosphere PCV ID received a marketing authorisation valid throughout the EU on 18 September 2020.

Further information on Mhyosphere PCV ID can be found on the Agency's website:  
[www.ema.europa.eu/medicines/veterinary/EPAR/mhyosphere-pcv-id](http://www.ema.europa.eu/medicines/veterinary/EPAR/mhyosphere-pcv-id).

This overview was last updated in 12-2020.