EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 July 2024
EMA/CVMP/303620/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Porcilis PCV M Hyo ID

Common name: Porcine circovirus and porcine enzootic pneumonia vaccine (inactivated)

On 18 July 2024, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Porcilis PCV M Hyo ID, emulsion for injection, intended for pigs. The applicant for this veterinary medicinal product is Intervet International B.V.

Porcilis PCV M Hyo ID is an immunological veterinary medicinal product containing porcine circovirus type 2, ORF2 capsid protein and *Mycoplasma hyopneumoniae*, strain J, inactivated (ATCvet code QI09AL08) as active substances. The product stimulates the development of active immunity against porcine circovirus type 2 and *Mycoplasma hyopneumoniae* in pigs.

The benefit of Porcilis PCV M Hyo ID is the active immunisation of pigs to reduce viremia, virus load in lungs and lymphoid tissues, and faecal virus shedding caused by porcine circovirus type 2 (PCV2) infection and severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection and to reduce the loss of daily weight gain during the finishing period in face of infections with PCV2 and/or *M. hyopneumoniae*.

The most common side effects are elevated temperature, injection site swelling and injection site scabs.

The full indication is:

For the active immunisation of pigs to reduce viremia, virus load in lungs and lymphoid tissues, and faecal virus shedding caused by porcine circovirus type 2 (PCV2) infection and severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection and to reduce the loss of daily weight gain during the finishing period in face of infections with PCV2 and/or *M. hyopneumoniae*.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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Onset of immunity:

PCV2: 2 weeks after vaccination,

M. hyopneumoniae: 4 weeks after vaccination.

Duration of immunity:

PCV2: 26 weeks after vaccination,

M. hyopneumoniae: 18 weeks after vaccination.

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC) which will be published in the Union Product Database (UPD) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Porcilis PCV M Hyo ID and therefore recommends the granting of the marketing authorisation.