10 July 2015
EMA/CVMP/354782/2015
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Porcilis PCV ID

Common name: Porcine circovirus vaccine (inactivated)

On 9 July 2015, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Porcilis PCV ID, emulsion for injection, intended for the active immunisation of pigs to reduce viraemia, virus load in lungs and lymphoid tissues and virus shedding caused by porcine circovirus type 2 (PCV2) infection. In addition, to reduce loss of daily weight gain and mortality associated with PCV2 infection. The applicant for this veterinary medicinal product is Intervet International B.V.

Porcilis PCV ID is a medicinal product containing inactivated porcine circovirus type 2 orf2 subunit antigen (ATCvet code QI09AA07) as active substance and it is intended for active immunization against PCV2 infection in finishing pigs.

The benefits of Porcilis PCV ID are the active immunisation of fattening pigs to reduce viraemia, virus load in lungs and lymphoid tissues and virus shedding caused by PCV2 infection. In addition, to reduce loss of daily weight gain and mortality associated with PCV2 infection. Onset of immunity was satisfactorily demonstrated at 2 weeks (14 days) post vaccination and duration of immunity was shown to last for 23 weeks (161 days) post vaccination.

The most common side effects are transient local reactions at the injection site.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) 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 ID and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.
[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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