13 September 2024
EMA/CVMP/413939/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Cirbloc M Hyo

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

On 12 September 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 *Cirbloc M Hyo emulsion for injection for pigs*. The applicant for this veterinary medicinal product is Ceva-Phylaxia Co. Ltd.

Cirbloc M Hyo is an immunological veterinary medicinal product containing *Mycoplasma hyopneumoniae*, strain 2940, inactivated, and ORF2 capsid protein of porcine circovirus type 2d as active substances, which act by stimulating active immunity against porcine circovirus type 2 and against *Mycoplasma hyopneumoniae*.

The benefits of Cirbloc M Hyo are its efficacy in reducing viraemia, virus load in lungs and lymphoid tissues, virus shedding caused by porcine circovirus type 2 (PCV2) infection, severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection, and reduction of the loss in body weight gain in pigs for fattening.

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

The full indication is:

"For the active immunisation of pigs to reduce:

- viraemia, virus load in lungs and lymphoid tissues, virus shedding caused by porcine circovirus type 2 (PCV2) infection,

- severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection,

- the loss in body weight gain.

[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: 3 weeks after vaccination

Duration of immunity:
PCV2: 23 weeks after vaccination
M. hyopneumoniae: 23 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 Cirbloc M Hyo and therefore recommends the granting of the marketing authorisation.