14 February 2025
EMA/CVMP/34688/2025
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

Porcilis ColiClos

Common name: *E. coli* and *C. perfringens* vaccine (inactivated) to provide passive immunity to pigs

On 12 February 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a group of variations to the terms of the marketing authorisation for the veterinary medicinal product Porcilis ColiClos. The marketing authorisation holder for this veterinary medicinal product is Intervet International B.V.

Porcilis ColiClos is currently authorised as suspension for injection. The variation is to replace the master seed by a new strain, to replace the current authorised site for the antigen manufacturing process and in process control tests by a new site, and to adapt the production process and in process control tests for the antigen.

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

[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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