28 May 2018
EMA/CVMP/281117/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Porcilis PCV M Hyo

Common name: porcine circovirus type 2 ORF2 subunit antigen / Mycoplasma hyopneumoniae inactivated

On 25 May 2018 the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Porcilis PCV M Hyo. The marketing authorisation holder for this veterinary medicinal product is Intervet International B.V.

Porcilis PCV M Hyo is currently authorised as an emulsion for injection. The variation was to modify the approved therapeutic indication to include an additional posology.

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 revised European public assessment report (EPAR) 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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