7 November 2025
EMADOC-1700519818-2563533
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

Mhyosphere PCV ID

International non-proprietary name (INN): Mycoplasma hyopneumoniae and porcine circovirus vaccine (inactivated, recombinant)

On 6 November 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 Mhyosphere PCV ID. The marketing authorisation holder for this veterinary medicinal product is Laboratorios HIPRA S.A.

Mhyosphere PCV ID is currently authorised for the active immunisation of pigs to reduce lung lesions associated with porcine enzootic pneumonia caused by *Mycoplasma hyopneumoniae*. Also, to reduce the incidence of these lesions (as observed in field studies); to reduce viraemia, virus load in lungs and lymphoid tissues and the duration of the viraemic period associated with diseases caused by Porcine circovirus type 2 (PCV2). Efficacy against PCV2 genotypes a, b and d has been demonstrated in field studies; and to reduce culling rate and the loss of daily weight gain caused by *Mycoplasma hyopneumoniae* and/or PCV2 related diseases (as observed at 6 months of age in field studies).

The variation concerns the update the product information due to new safety data. The changes are reflected in the SPC in section 3.6, and the corresponding PI in section 7. Adverse events.

There is a change on the frequency of the elevated temperature from common to very common. The mean temperature increase is 1.6 ºC, and less than 2.3 ºC in individual pigs. It subsides spontaneously within 24 – 48 hours without treatment. The injection site inflammation is described now as slight to moderate inflammation (between 0.3-5 cm) at the inoculation site, that can be observed during the first week after vaccination. One or two weeks later, these local reactions can reappear. Local reactions disappear completely within approximately 3 weeks after vaccination without treatment.

[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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

In addition, editorial changes/minor typographical corrections are made to the product information that do not alter the meaning of the text.

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.