21 June 2024
EMA/CVMP/265921/2024
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

Suvaxyn PRRS MLV

Common name: Porcine respiratory and reproductive syndrome virus vaccine (live)

On 19 June 2024, 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 Suvaxyn PRRS MLV. The marketing authorisation holder for this veterinary medicinal product is Zoetis Belgium.

Suvaxyn PRRS MLV is currently authorised as lyophilisate and solvent for suspension for injection. The variation is to change the product information related to the use in lactating sows and consequential adverse events in this subcategory of animals.

Based on the new data presented, the use of Suvaxyn PRRS MLV in lactating sows is acceptable; the identified adverse events for this subcategory of animals when using Suvaxyn PRRS MLV are described as of very common observation, which include elevated temperature, decreased appetite and injection site swelling.

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.

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