17 April 2026
EMADOC-1700519818-3056849
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

Startvac

Common name: Staphylococcus aureus and coagulase-negative staphylococci and Escherichia coli J5 vaccine (inactivated)

On 16 April 2026, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Startvac. The marketing authorisation holder for this veterinary medicinal product is Laboratorios HIPRA S.A.

Startvac is an inactivated vaccine for herd immunisation of healthy cows and heifers to reduce the incidence of sub-clinical mastitis and the incidence and the severity of the clinical signs of clinical mastitis caused by *Staphylococcus (S.) aureus*, coliforms and coagulase-negative staphylococci in dairy cattle herds with recurring mastitis problems. The vaccine consists of an emulsion for intramuscular injection.

The variation concerns G.I.9: other variations not specifically covered elsewhere in chapter G which involve the submission of studies to the competent authority, including additional clinical and non-clinical studies, including BE-studies. The purpose of this variation was to change the immunisation scheme so that the product could be administered independently of the parturition date of the animals. More specifically, the applicant proposed to administer the current primary vaccination consisting of 3 doses regardless of the expected parturition date or gestation phase of the animals followed by booster doses every three months to maintain vaccine protection for longer periods instead of repeating the full primary vaccination scheme (three vaccinations around the third trimester and early lactation) with each gestation. The proposed vaccination regime would result in a rolling vaccination of dairy cattle herds with recurring mastitis problems.

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

[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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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.