10 December 2021
EMA/CVMP/714359/2021
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

Improvac

Common name: gonadotropin releasing factor analogue diptheria toxoid conjugate

On 9 December 2021, 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 Improvac. The marketing authorisation holder for this veterinary medicinal product is Zoetis Belgium SA.

Improvac is currently authorised for male pigs as a solution for injection indicated for the induction of antibodies against GnRF to produce a temporary immunological suppression of testicular function. The variation concerns the indication by adding the suppression of oestrus in female pigs and subsequent changes to the product information.

Detailed conditions for the use of this product are described in the 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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