18 July 2025
EMA/CVMP/31091/2025
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Cevac Reomune

Common name: Avian reovirus vaccine (inactivated)

On 17 July 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Cevac Reomune, emulsion for injection, intended for chickens (breeders). The applicant for this veterinary medicinal product is Filavie.

Cevac Reomune is an immunological veterinary medicinal product containing inactivated avian reovirus, strains S1133 and 11-12523 (ATCvet code QI01AA04) as active substances.

The benefit of Cevac Reomune is its efficacy on eliciting active immunisation of broiler breeders to provide a passive immunisation to the progeny to reduce clinical signs of tenosynovitis induced by avian reovirus infection (serotype S1133 and variant serotype 11-12523).

The most common side effect is injection site swelling.

The full indication is: *"For active immunisation of broiler breeders to provide a passive immunisation to the progeny to reduce clinical signs of tenosynovitis induced by avian reovirus infection serotype S1133 and variant serotype 11-12523.*

Onset of immunity

In hens: *3 weeks after the second vaccination (demonstrated by serology)*

In the progeny: *From the 1st day of life*

Duration of immunity:

In hens: *at least 48 weeks after the second vaccination (demonstrated by serology)*

In the progeny: *14 days of age"*

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

[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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(SPC) which will be published in the Union Product Database (UPD) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Cevac Reomune and therefore recommends the granting of the marketing authorisation.