



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Veterinary Medicinal Products

Summary of opinion¹ (initial authorisation)

Cevac Salmune ETI K

Common name: *Salmonella* Enteritidis, *Salmonella* Typhimurium and *Salmonella* Infantis vaccine (inactivated) for chickens

On 18 July 2024, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion², recommending the granting of a marketing authorisation for the veterinary medicinal product Cevac Salmune ETI K suspension for injection for chickens. The applicant for this veterinary medicinal product is CEVA-Phylaxia Zrt.

Cevac Salmune ETI K is an immunological veterinary medicinal product containing *Salmonella enterica*, subsp. *enterica*, serovar Enteritidis, strain 038-90, inactivated; *Salmonella enterica*, subsp. *enterica*, serovar Typhimurium, strain 076-94, inactivated; and *Salmonella enterica*, subsp. *enterica*, serovar Infantis, strain SM-595, inactivated (ATCvet code QI01AB01) as active substance, which act by stimulating active immunity against these three serovars of *S. enterica* subsp. *enterica*.

The benefit of Cevac Salmune ETI K is its efficacy in active immunisation of 10-weeks-old breeder and layer chickens. The most common side effect is injection site reaction.

The full indication is:

“For the active immunisation of chickens (breeders and layers) from 10 weeks of age to reduce faecal excretion of *Salmonella* Enteritidis, *Salmonella* Typhimurium and *Salmonella* Infantis.

Salmonella Enteritidis:

Onset of immunity: 4 weeks after 2nd vaccination

Duration of immunity: 69 weeks after 2nd vaccination

Salmonella Typhimurium:

Onset of immunity: 4 weeks after 2nd vaccination

Duration of immunity: 71 weeks after 2nd vaccination

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.



Salmonella Infantis:

Onset of immunity: 4 weeks after 2nd vaccination

Duration of immunity: 44 weeks after 2nd vaccination"

Detailed conditions for the use of this product are described in the summary of product characteristics (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 Salmune ETI K and therefore recommends the granting of the marketing authorisation.