17 June 2022
EMA/CVMP/560050/2022
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Evanovo

Common name: Coccidiosis vaccine live for chickens

On 15 June 2022, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Evanovo, suspension and solvent for suspension for injection, intended for chicken embryonated eggs. The applicant for this veterinary medicinal product is Laboratorios Hipra, S.A.

Evanovo is a live attenuated parasitic vaccine against coccidiosis in chickens containing *Eimeria acervulina*, strain 044, live / *Eimeria maxima*, strain 013, live / *Eimeria praecox*, strain 007, live / *Eimeria tenella*, strain 004, live (ATCvet code QI01AN01) as active substance.

The benefits of Evanovo are its efficaciousness for the active immunisation of chickens to reduce clinical signs (diarrhoea), intestinal lesions and oocysts output associated with coccidiosis caused by *Eimeria acervulina*, *Eimeria maxima* and *Eimeria praecox*, and for the reduction of clinical signs, intestinal lesions and oocysts output associated with coccidiosis caused by *Eimeria tenella*. The onset of immunity is 21 days of age, and the duration of immunity is 63 days of age. Evanovo increases the range of available treatment possibilities and routes of administration for live, attenuated coccidiosis vaccines for chickens with consequent indirect benefit on reducing the use of anticoccidial agents. Evanovo is generally well tolerated at the recommended dose.

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) 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 Evanovo and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.
[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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