7 December 2018
EMA/CVMP/808273/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

EVANT

Common name: Coccidiosis vaccine live for chickens

On 6 December 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product EVANT, suspension and solution for oral spray, intended for active immunisation of chicks from 1 day of age to reduce intestinal lesions and oocysts output associated with coccidiosis caused by *Eimeria acervulina, Eimeria maxima, Eimeria mitis, Eimeria praecox* and *Eimeria tenella* and to reduce clinical signs (diarrhoea) associated with *Eimeria acervulina, Eimeria maxima* and *Eimeria tenella*. The applicant for this veterinary medicinal product is LABORATORIOS HIPRA, S.A.

EVANT is a live attenuated parasitic vaccine against coccidiosis in chickens (ATCvet code QI01AN01) containing sporulated oocysts as active substances *Eimeria acervulina* (strain 003), *Eimeria maxima* (strain 013), *Eimeria mitis* (strain 006), *Eimeria praecox* (strain 007) and *Eimeria tenella* (strain 004).

The benefits of EVANT are its prophylactic immunisation of chickens, used as short-lived chickens only, against five major disease-causing coccidiosis to reduce intestinal lesions and oocysts output and to reduce clinical signs (diarrhoea) associated with *Eimeria acervulina, Eimeria maxima* and *Eimeria tenella*. Chickens can be vaccinated from 1 day of age with the onset of immunity established 14 days after vaccination. Duration of immunity is 63 weeks after vaccination in an environment that permits the recycling of oocysts in vaccinated birds.

EVANT is generally well tolerated at the recommended dose.

Detailed conditions for the use of this product will be 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 EVANT 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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