16 June 2017
EMA/CVMP/292749/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

VEPURED

Common name: *E. coli* verotoxoid vaccine (inactivated recombinant)

On 15 June 2017, 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 VEPURED, suspension for injection, intended for active immunisation of piglets from 2 days of age to prevent mortality and reduce clinical signs of oedema disease (caused by verotoxin 2e produced by *E. coli*) and to reduce the loss of daily weight gain during the finishing period in face of infections with verotoxin 2e producing *E. coli* until slaughter from 164 days of age. The applicant for this veterinary medicinal product is Laboratorios Hipra, S.A.

VEPURED is an immunological veterinary medicinal product containing recombinant verotoxin 2e (ATCvet code QI09AB02) that stimulates an active immunity against VT2e toxin.

The benefits of VEPURED are its prophylactic immunisation of pigs from 2 days of age against verotoxin 2e producing *E. coli* responsible for oedema disease. The onset of immunity is 21 days after vaccination with a duration of immunity of 112 days. VEPURED is well tolerated at the recommended dose. The most common side effects are mild inflammation at the injection site and mild depression that typically resolve without treatment.

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 VEPURED 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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