12 May 2014
EMA/CVMP/158588/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

ERYSENG

Common name: *Erysipelothrix rhusiopathiae*

On 8 May 2014, 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 ERYSENG, a suspension for injection, intended for the active immunisation of male and female pigs to reduce clinical signs (skin lesions and fever) of swine erysipelas caused by *Erysipelothrix rhusiopathiae*, serotype 1 and serotype 2.

The applicant for this veterinary medicinal product is Laboratorios HIPRA, S.A.

The active substance of ERYSENG is the inactivated *Erysipelothrix rhusiopathiae*, strain R32E11. ERYSENG is an inactivated bacterial vaccine for pigs (QI09AB03) that stimulates active immunisation against swine erysipelas.

The benefit of ERYSENG is the active immunisation of male and female pigs to reduce clinical signs (skin lesions and fever) of swine erysipelas caused by *Erysipelothrix rhusiopathiae*, serotype 1 and serotype 2.

The most common side effects are the mild to moderate inflammation at the injection site that typically resolves within four days but in some cases may persist for up to 12 days post-vaccination, and a transient increase in body temperature within the first 6 hours after vaccination, which spontaneously resolves within 24 hours.

The onset of immunity is three weeks after completion of the basic vaccination scheme and the duration of immunity is six months.

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 to risk balance for ERYSENG 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 within 90 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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