28 May 2018
EMA/CVMP/273331/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

UBAC

Common name: Streptococcus uberis vaccine (inactivated)

On 25 May 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 UBAC, emulsion for injection intended for active immunisation of healthy cows and heifers to reduce the incidence of clinical intramammary infection caused by *Streptococcus uberis*, to reduce the somatic cell count in *Streptococcus uberis* positive quarter milk samples and to reduce milk production losses caused by *Streptococcus uberis* intramammary infections. The applicant for this veterinary medicinal product is Laboratorios Hipra, S.A.

UBAC is an immunological medicinal product containing Lipoteichoic acid (LTA) within the Biofilm Adhesion component (BAC) including *Streptococcus uberis*, strain 5616 (ATCvet code QI02AB) as active substance.

The benefits of UBAC are its reduction of the incidence of clinical intramammary infection caused by *Streptococcus uberis*, reduction of the somatic cell count in *Streptococcus uberis* positive quarter milk samples and reduction of milk production losses caused by *Streptococcus uberis* intramammary infections which was investigated in well-designed laboratory and field studies conducted to an acceptable standard.

The onset of immunity is approximately 36 days after the second dose and the duration of immunity is approximately the first 5 months of lactation.

The most common side effects are local reactions at the injection site and transient temperature increase.

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.

[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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The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for UBAC and therefore recommends the granting of the marketing authorisation.