10 October 2014
EMA/CVMP/575913/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Bovela

Common name: Bovine viral diarrhoea vaccine (modified live)

On 9 October 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 Bovela, lyophilisate and solvent for suspension for injection, intended for active immunisation of pregnant cattle against bovine viral diarrhoea virus.

The applicant for this veterinary medicinal product is Boehringer Ingelheim Vetmedica GmbH.

The active substances of Bovela are modified live bovine virus diarrhoea virus type 1 (strain ke-9) and modified live bovine virus diarrhoea virus type 2 (strain ny-93). This is an immunological medicinal product (ATCvet code QI02AD02).

The benefits of Bovela are the active immunisation of cattle from 3 months of age to reduce hyperthermia and to minimise the reduction of leukocyte count caused by bovine viral diarrhoea virus (BVDV-1 and BVDV-2) and to reduce virus shedding and viraemia caused by BVDV-2, and also the active immunisation of cattle against BVDV-1 and BVDV-2, to prevent the birth of persistently infected calves caused by transplacental infection. The most common side effects are transient mild swellings or nodules and an increase in body temperature.

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 Bovela 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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