10 June 2011
EMA/CVMP/506555/2010
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

ZULVAC 1 Bovis

Inactivated Bluetongue virus, serotype 1, strain BTV-1

On 8 June 2011 the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,[2] recommending the granting of a marketing authorisation under exceptional circumstances for the veterinary medicinal product ZULVAC 1 Bovis. The applicant for this veterinary medicinal product is Pfizer Limited.

The active substance of ZULVAC 1 Bovis is the inactivated Bluetongue virus, serotype 1, strain BTV-1, an immunological veterinary medicinal product ATC code, QI04AA02 indicated to develop an active immunisation of cattle and to prevent viraemia.

The benefits of ZULVAC 1 Bovis are its prophylactic immunisation to protect cattle against infection with BTV serotype 1. The vaccine has been proven to prevent viraemia. Prevention of viraemia directly benefits the animal in that this ensures reduction of clinical signs or loss of condition.

The most common side effect is a transient increase in rectal temperature for up to 1.6 °C, may occur the 3rd day after injection and then return to normal values. After the second and third vaccination the rectal temperature increases of up to 1.3 °C and 2.8 °C respectively. This may occur one day after the injection, and then return to normal values. No adverse reactions (general or local reaction) were observed after the 1st, 2nd and 3rd administration of a single dose of vaccine to calves.

The approved indication is for the active immunisation of cattle from 2½ months of age for the prevention* of viraemia caused by Bluetongue Virus, serotype 1.

Onset of immunity: 15 days after completion of the primary vaccination course.

Duration of immunity: 12 months

[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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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 ZULVAC 1 Bovis and therefore recommends the granting of the marketing authorisation under exceptional circumstances.[3]

[3] Marketing authorisation under exceptional circumstances refers to the fact that in exceptional circumstances an authorisation may be granted subject to certain specific obligations, to be reviewed annually.