11 February 2011
EMA/CVMP/343772/2010
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

BLUEVAC BTV8

Inactivated vaccine against bluetongue disease for sheep and cattle

On 9 February 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[3] for the veterinary medicinal product BLUEVAC BTV8 a suspension for injection, intended for the active immunisation of sheep and cattle for the prevention of viraemia and reduction of clinical signs caused by bluetongue virus serotype 8 in sheep from 2.5 months of age and the prevention of viraemia caused by Bluetongue Virus, serotype 8 in cattle from 2.5 months of age.

The applicant for this veterinary medicinal product is CZ Veterinaria S.A.

The active substance of BLUEVAC BTV8 is the inactivated Bluetongue Virus (BTV) Serotype 8.

The benefit of BLUEVAC BTV8 is the stimulation of active immunity in sheep and cattle against bluetongue virus serotype 8, resulting in prevention of viraemia for both sheep and cattle and reduction of clinical signs for sheep.

The most common side effects are an average increase in body temperature that can occasionally be observed varying between 0.5 and 1.0 ºC in sheep and cattle and should last no longer than 24 to 48 hours. Transient fever was observed in rare cases. Occasionally, temporary local reactions occur at the injection site in the form of a normally painless nodule of 0.5 to 1 cm in sheep and of 0.5 to 3 cm in cattle which disappear within 14 days, at the latest. In some cases loss of appetite can occur.

The approved indication is:

"***Sheep***

For the active immunisation of sheep from 2.5 months of age to prevent viraemia and to reduce clinical signs caused by bluetongue virus serotype 8.*

[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.
[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.

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(Cycling value (Ct) ≥ 36 by a validated RT-PCR method, indicating no presence of viral genome)

Onset of immunity: 20 days after the second dose
Duration of immunity: 1 year after the second dose.

Cattle

For the active immunisation of cattle from 2.5 months of age to prevent viraemia caused by bluetongue virus serotype 8.*

(Cycling value (Ct) ≥ 36 by a validated RT-PCR method, indicating no presence of viral genome)

Onset of immunity: 31 days after the second dose.
Duration of immunity: 1 year after the second dose.''

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 BLUEVAC BTV8 and therefore recommends the granting of the marketing authorisation under exceptional circumstances.