17 January 2025
EMA/CVMP/584037/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Bluevac-3

Common name: Bluetongue virus vaccine (inactivated)

On 15 January 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Bluevac-3, suspension for injection, intended for cattle and sheep. The applicant for this veterinary medicinal product is CZ Vaccines S.A.U.

Bluevac-3 is a vaccine containing inactivated bluetongue virus, serotype 3, BTV-3/NET2023 (ATCvet code QI04AA02) as active substance. The vaccine is intended to stimulate the active immunity of sheep and cattle against bluetongue virus serotype 3.

The benefits of Bluevac-3 are its efficacy for the active immunisation of sheep to reduce the viraemia, mortality and clinical signs caused by the serotype 3 of the bluetongue virus and for the active immunisation of cattle to reduce the viraemia against the serotype 3 of the bluetongue virus.

The most common side effects are injection site swelling (very common) and elevated temperature (common).

The full indication is:

Sheep:
For active immunisation of sheep to reduce the viraemia, mortality and clinical signs caused by the serotype 3 of the bluetongue virus.
Onset of immunity: 3 weeks after completion of the primary vaccination scheme.
Duration of immunity: not established.
Cattle:
For active immunisation of cattle to reduce the viraemia against the serotype 3 of the bluetongue virus.
Onset of immunity: 3 weeks after completion for the primary vaccination scheme.
Duration of immunity: not established.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[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 are described in the summary of product characteristics (SPC) which will be published in the Union Product Database (UPD) 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-risk balance for Bluevac-3 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.