17 February 2023
EMA/CVMP/42050/2023
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Bovilis Nasalgen-C

Common name: Bovine coronavirus vaccine, live attenuated

On 15 February 2023, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Bovilis Nasalgen-C, nasal spray, lyophilisate and solvent for suspension, intended for cattle. The applicant for this veterinary medicinal product is Intervet International B.V.

Bovilis Nasalgen-C is an immunological veterinary medicinal product containing bovine coronavirus, strain CA25, live attenuated (ATCvet code QI02AD10) as active substance, and intended to stimulate active immunity against bovine coronavirus by stimulating the gene expression for receptors and cytokines in anti-viral innate immune responses.

The benefits of Bovilis Nasalgen-C are its stimulation of the active immunisation of cattle from the day of birth onwards to reduce clinical signs of upper respiratory tract disease and nasal viral shedding from infection with bovine coronavirus. The most common side effects are nasal discharge, increased respiratory rate, cough and elevated temperature up to 40.7 °C which normally resolves within three days (>1 animal / 10 animals treated) and ocular discharge (1 to 10 animals / 100 animals treated). Bovilis Nasalgen-C is generally well tolerated at the recommended dose, adverse reactions (same as above) are only seen after administration of a 10-fold overdose of the vaccine.

Onset of immunity: 5 days.
Duration of immunity: 12 weeks.

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

[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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favourable benefit-risk balance for Bovilis Nasalgen-C and therefore recommends the granting of the marketing authorisation.