

24 May 2019
EMA/CVMP/252872/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (initial authorisation)

NASYM

Common name: Bovine respiratory syncytial virus vaccine (live)

On 22 May 2019, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion², recommending the granting of a marketing authorisation for the veterinary medicinal product NASYM, lyophilisate and solvent for suspension for injection or nasal spray, intended for cattle. The applicant for this veterinary medicinal product is LABORATORIOS HIPRA, S.A.

NASYM is an immunological medicinal product containing a live attenuated bovine respiratory syncytial virus, (ATCvet code QI02AD04) as active substance.

The benefits of NASYM are its efficacy in the treatment of cattle against bovine respiratory syncytial virus infection to reduce virus shedding and respiratory clinical signs. The onset of immunity is 21 days after administration of one dose by the nasal route and 21 days after the second dose of the two dose intramuscular vaccination schedule. The duration of immunity is 2 months after nasal vaccination and 6 months after intramuscular vaccination. The most common side effect is a slight alteration of faecal consistency.

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-risk balance for NASYM 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 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.