



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/CVMP/473135/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (initial authorisation)

Nobivac Myxo-RHD PLUS

Common name: Myxomatosis and rabbit haemorrhagic viral disease vaccine (live recombinant)

On 12 September 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 Nobivac Myxo-RHD PLUS, lyophilisate and solvent for suspension for injection, intended for rabbits. The applicant for this veterinary medicinal product is Intervet International B.V.

Nobivac Myxo-RHD PLUS is a live recombinant vaccine containing two live myxoma vectored RHD viruses (ATCvet code QI08AD) as active substances.

The benefit of Nobivac Myxo-RHD PLUS is the stimulation of active immunity in rabbits from 5 weeks of age onwards resulting in a reduction of mortality and clinical signs of myxomatosis and rabbit haemorrhagic disease (RHD) caused by classical RHD virus (RHDV1) and RHD type 2 virus (RHDV2). The onset of immunity is three weeks and the duration of immunity is one year.

Nobivac Myxo-RHD PLUS is generally well tolerated at the recommended dose. The most common side effects are small, non-painful swellings at the injection site which resolve within three weeks after vaccination and a transient increase in body temperature. In very rare cases, local reactions at the injection site (necrosis, scabs or hair loss) may occur in pet rabbits. Serious hypersensitivity reactions, which may be fatal, and the appearance of mild clinical signs of myxomatosis within 3 weeks of vaccination may also occur in very rare cases.

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 Nobivac Myxo-RHD PLUS 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.

