15 July 2011
EMA/CVMP/504724/2011
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

Nobivac Myxo-RHD

Live myxoma vectored RHD virus strain 009

On 14 July 2011, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,[2] recommending the granting of a marketing authorisation for the veterinary medicinal product Nobivac Myxo-RHD, lyophilisate and solvent for suspension for injection, intended for active immunisation of rabbits to reduce mortality and clinical signs of myxomatosis and to prevent mortality due to rabbit haemorrhagic disease (RHD).

Onset of immunity: 3 weeks.

Duration of immunity: 1 year.

The applicant for this veterinary medicinal product is Intervet International BV.

The active substance of Nobivac Myxo-RHD is live myxoma vectored RHD virus strain 009. It is an immunological medicinal product ATCvet code: QI08AD.

The benefits of Nobivac Myxo-RHD are that RHD protection could be demonstrated when serologically naïve rabbits were vaccinated. With regard to the efficacy against myxoma virus infections, reduction of mortality and clinical signs could be demonstrated. The vaccine does not contain any adjuvant or preservative. The most common side effects are a transient increase in temperature and a small non-painful swelling at the injection site which will resolve within 3 weeks.

The approved indication is: For active immunisation of rabbits from 5 weeks of age onwards to reduce mortality and clinical signs of myxomatosis and to prevent mortality due to rabbit haemorrhagic disease.

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.

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Nobivac Myxo-RHD and therefore recommends the granting of the marketing authorisation.