9 October 2020
EMA/CVMP/500514/2020
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Nobivac DP Plus

Common name: Canine distemper vaccine (live) and canine parvovirus vaccine (live recombinant)

On 7 October 2020, 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 DP Plus, lyophilisate and solvent for suspension for injection, intended for dogs (puppies). The applicant for this veterinary medicinal product is Intervet International B.V.

Nobivac DP Plus is an immunological medicinal product containing canine distemper virus, live and canine parvovirus, live recombinant (ATCvet code QI07AD03), as active substances.

The benefit of Nobivac DP Plus is the stimulation of active immunity in puppies against canine parvovirus (CPV) and canine distemper virus (CDV) infections. Hence, helping very young puppies to overcome the so-called "window of susceptibility" or "immunity gap" which is a dangerous period of time during which maternally derived antibodies have fallen below protective levels against virulent field strains but are still able to interfere with the efficacy of the vaccination. The very short onset of immunity (3 days for CPV and 7 days for CDV) is a benefit for those puppies, which do not have maternally derived antibodies and are therefore fully susceptible for infections with CDV and CPV. The most common side effects are a small, non-painful swelling (maximum 1 cm diameter) at the injection site very commonly observed within the first week after vaccination. The swelling will resolve completely within a few days. Reduced activity can occur within 4 hours after vaccination.

The full indication is: For the active immunisation of puppies from 4 weeks of age onwards to prevent clinical signs and mortality of canine distemper virus infection and canine parvovirus infection and to prevent viral excretion following canine distemper virus infection and following canine parvovirus infection.
Onset of immunity: For canine distemper virus: 7 days; for canine parvovirus: 3 days.
Duration of immunity: 8 weeks.

[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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Detailed conditions for the use of this product are 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 DP Plus and therefore recommends the granting of the marketing authorisation.