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EPAR summary for the public

Vectormune ND

Newcastle disease and Marek's disease vaccine (live recombinant)

This is a summary of the European public assessment report (EPAR) for Vectormune ND. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use Vectormune ND.

For practical information about using Vectormune ND, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is Vectormune ND and what is it used for?

Vectormune ND is a veterinary vaccine used to protect chickens against Newcastle disease (ND) and Marek's disease (MD).

ND is a viral infection of chickens which causes gasping and coughing, nervous signs (drooping wings, twisting of the head and neck, circling and paralysis), swelling of the tissues around the eyes and neck, greenish watery diarrhoea and reduced egg production.

MD is a herpesvirus infection of chickens which can cause paralysis of the wings and legs and causes tumours in various organs. Chickens become infected at an early age via inhalation of dander (flakes of skin) containing the virus which can remain infectious for several months after being shed from the body. Birds infected with MD virus can be carriers and shedders of the virus for life. The vaccine protects against a type of Marek disease virus that can cause visible infection.

The active substance in Vectormune ND is a turkey herpesvirus (rHVT/ND) that does not cause disease in chickens and has been modified so that it also produces one of the proteins of a strain of Newcastle disease virus (D-26 lentogenic strain).

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How is Vectormune ND used?

Vectormune ND is available as a suspension and solvent to be made into a suspension for injection and can only be obtained with a prescription. The vaccine can be given to one-day-old chicks as a single injection under the skin or directly into 18-day-old eggs containing embryos (unhatched developing chicks). For ND protection starts at 3 weeks of age and lasts until 9 weeks of age for broilers (chickens bred for meat) and 18 weeks of age for layers (chickens bred for egg production). For MD protection starts at one week of age and lasts for the risk period of infection with MD.

How does Vectormune ND work?

Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. The modified turkey herpesvirus in Vectormune ND is closely related to MD herpesvirus and will also produce the fusion protein which forms part of the outer coat of ND virus. When Vectormune ND is given to chickens or eggs, the animals' immune system recognises the virus as 'foreign' and makes antibodies against it. In the future if the animals are exposed to a similar virus and/or to a virus expressing a similar fusion protein, the immune system will be able to respond more quickly. This will help protect the chickens against ND and MD.

What benefits of Vectormune ND have been shown in studies?

Two field studies were conducted in around 120,000 broiler chickens to evaluate the effects of the vaccine. Since no natural outbreaks of ND and MD occurred the chickens were challenged (exposed to infection) in the laboratory.

In the first field study a group of 18-day-old eggs containing embryos and a group of one-day-old chicks were vaccinated with Vectormune ND. Five-week-old chickens from the vaccinated eggs were challenged with ND virus and 91% of vaccinated chickens were protected compared with no protection in the unvaccinated group. Five-week-old chickens from the vaccinated one-day-old chicks were challenged with ND virus and 81% of vaccinated chickens were protected compared with no protection in the unvaccinated group. Nine-day-old chickens from vaccinated eggs were challenged with MD virus and 88% of the chickens were protected compared with 9-12% in the unvaccinated group. Nine-day-old broilers from the chicks vaccinated at one-day-old were challenged with MD virus and Vectormune ND provided protection to 90% of the chickens compared with 9-12% in the unvaccinated group.

In the second field study, a group of 18-day-old eggs containing embryos and a group of one-day-old chicks were vaccinated with Vectormune ND. Four-week-old chickens from the group of one-day-old vaccinated chicks were challenged with ND virus and Vectormune ND provided protection in 95% of the chickens compared with 0–10% in the non-vaccinated group. Four-week-old chickens from vaccinated eggs were challenged with ND virus and 86% of the chickens were protected compared with 0–10% in the unvaccinated group. Nine-day-old broilers from vaccinated eggs were challenged with MD virus and 85% of the chickens were protected compared with 9% in the unvaccinated group. Nine-day-old broilers from the group of chicks vaccinated at one-day-old were challenged with MD virus and 82% of the chickens were protected compared with 12% in the unvaccinated group.

In a third field study around 10,000 one-day-old layer chickens were vaccinated with Vectormune ND and a similar number with a vaccine against ND alone. No signs of MDV or NDV outbreaks were detected from samples taken from both groups at days 35, 66, 102 and completion at day 118. Twenty-two Vectormune ND vaccinated day-old layer chickens from this study were challenged at day 21 in the laboratory with ND strain and had no clinical signs for up to 2 weeks after challenge while all of 12 unvaccinated birds used for comparison died.

What are the risks associated with Vectormune ND?

Since Vectormune ND is a live vaccine, the vaccine strain is excreted from vaccinated birds and may spread to turkeys. Safety studies have shown that the strain is safe for turkeys. However, precautionary measures must be followed in order to avoid direct or indirect contact between vaccinated chickens and turkeys.

There are no known side effects with Vectormune ND. For the full list of restrictions, see the package leaflet.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

Safety information has been included in the summary of product characteristics and the package leaflet for Vectormune ND, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

As the vaccine is stored in liquid nitrogen, it is important that any handling is done by appropriately trained personnel in a well-ventilated area and that precautions are taken when preparing the vaccine. For further information see the summary of product characteristics.

What is the withdrawal period in food-producing animals?

The withdrawal period is the time required after administration of a medicine before an animal can be slaughtered and the meat used for human consumption. It is also the time required after administration of a medicine before eggs may be used for human consumption.

The withdrawal period for meat and eggs from chickens treated with Vectormune ND is ‘zero’ days, which means that there is no mandatory waiting time.

Why is Vectormune ND approved?

The Agency’s Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Vectormune ND’s benefits are greater than its risks and recommended that it be approved for use in the EU.

Other information about Vectormune ND

The European Commission granted a marketing authorisation valid throughout the EU for Vectormune ND on 8 September 2015.

The full EPAR for Vectormune ND can be found on the Agency’s website: ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports. For more information about treatment with Vectormune ND, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in January 2018.