



EMA/391280/2017  
EMEA/V/C/004422

## Innovax-ND-IBD (*avian Newcastle disease, infectious bursal disease and Marek's disease vaccine (live recombinant)*)

An overview of Innovax-ND-IBD and why it is authorised in the EU

### **What is Innovax-ND-IBD and what is it used for?**

Innovax-ND-IBD is a veterinary vaccine used to protect chickens against Newcastle disease (ND), infectious bursal disease (IBD) 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.

IBD, also known as Gumboro disease, is a viral infection of chickens associated with death at 3-6 weeks of age. It can make birds more prone to other diseases and can interfere with effective vaccination.

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.

Innovax-ND-IBD contains a live modified strain of turkey herpesvirus called strain HVP360. The turkey herpesvirus strain HVP360 has been modified so that it will produce proteins from ND virus and IBD virus.

### **How is Innovax-ND-IBD used?**

Innovax-ND-IBD 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 in the neck or directly into 18 – 19-day-old chicken eggs containing embryos (unhatched developing chicks). Protection against ND starts 4 weeks after vaccination and lasts 60 weeks. Protection against IBD starts 3 weeks after vaccination and lasts 60 weeks.

Protection against MD starts 9 days after vaccination and lasts for life.



For more information about using Innovax-ND-IBD, see the package leaflet or contact your veterinarian or pharmacist.

## **How does Innovax-ND-IBD work?**

Innovax-ND-IBD is a vaccine containing turkey herpesvirus serotype 3, a type of herpesvirus which does not cause disease in chickens but which is similar to the virus that causes MD. The virus in the vaccine has been modified so that it also makes proteins from ND and IBD viruses. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. When Innovax-ND-IBD is given to chickens, the animals' immune system recognises the virus as 'foreign' and makes antibodies against its proteins. In the future if the animals are exposed to similar proteins the immune system will be able to respond more quickly. This will help protect the chickens against ND, IBD and herpesvirus infections like MD.

## **What benefits of Innovax-ND-IBD have been shown in studies?**

Vaccinated chickens were taken from a field study and challenged (brought in contact with the viruses) in the laboratory to show protection after vaccination:

- for ND, 60% of vaccinated chickens did not develop ND when challenged at 4 weeks after vaccination and 95% of vaccinated chickens were protected 6 weeks after vaccination;
- for IBD, vaccinated birds were challenged at 3, 4, 6 and 8 weeks after vaccination. Vaccinated birds had a protection level of between 81% and 95% against disease signs;
- for MD, 87% of the vaccinated chickens were protected against challenge at 9 days after vaccination.

In a further study, chicks were vaccinated at 1 day of age and then challenged in the laboratory at 9, 50 and 60 weeks of age. For ND, 100% of vaccinated chickens were protected 60 weeks after vaccination. For IBD, vaccinated chickens were found to have protective antibodies 58 weeks after vaccination, suggesting that protection can last until 60 weeks.

Similar challenges were carried out after hatching to show the effects of vaccination of chicken eggs:

- for ND, 92% of chickens from vaccinated eggs did not develop ND when challenged at 46 days after vaccination;
- for IBD, 100% of vaccinated chickens did not develop IBD when challenged at 46 days after vaccination;
- for MD, 91% of chickens from vaccinated eggs did not develop MD when challenged at 8 days of age.

## **What are the risks associated with Innovax-ND-IBD?**

Since Innovax-ND-IBD is a live vaccine, the vaccine strain can be passed into the environment from vaccinated chickens and may spread to turkeys. Safety studies have shown that the strain is safe for turkeys, however, precautionary measures must be followed to avoid direct or indirect contact between vaccinated chickens and turkeys.

There are no known side effects. 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 Innovax-ND-IBD, 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 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 Innovax-ND-IBD is 'zero' days, which means there is no mandatory waiting time.

## **Why is Innovax-ND-IBD authorised in the EU?**

The European Medicines Agency decided that Innovax-ND-IBD's benefits are greater than its risks and recommended it can be authorised for use in the EU.

## **Other information about Innovax-ND-IBD**

Innovax-ND-IBD received a marketing authorisation valid throughout the EU on 22 August 2017.

The full EPAR for Innovax-ND-IBD can be found on the Agency's website:  
[ema.europa.eu/medicines/veterinary/EPAR/innovax-nd-ibd](http://ema.europa.eu/medicines/veterinary/EPAR/innovax-nd-ibd).

This overview was last updated in 11-2020.