



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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

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

### What is Ultifend ND IBD and what is it used for?

Ultifend ND IBD is a veterinary vaccine used to protect chickens against three separate viral diseases: 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 young chickens that reduces their immunity (body's ability to fight disease) and can lead to their death at 3 to 6 weeks of age. Signs of chickens infected with IBD include trembling, ruffled feathers, poor appetite, dehydration, diarrhoea, huddling and depression.

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. Chickens infected with MD virus can be carriers and shedders of the virus for life.

Ultifend ND IBD contains a live strain of turkey herpesvirus (strain rHVT/ND/IBD) that has been modified to produce proteins from ND virus and IBD virus.

### How is Ultifend ND IBD used?

The medicine can only be obtained with a prescription.

Ultifend ND IBD is available as a concentrate and solvent for suspension for injection. The vaccine can be given to one-day-old chicks as a single injection under the skin of the neck or directly into 18-day-old chicken eggs containing embryos (unhatched developing chicks).

Only healthy animals should be vaccinated, and all chickens in a flock should be vaccinated at the same time.

Protection against ND starts 4 weeks after vaccination and lasts 9 weeks in broiler chickens and 18 weeks in layer chickens. Protection against IBD starts 3 weeks after vaccination in broiler chickens and

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4 weeks in layer chickens, and lasts 9 weeks. Protection against MD starts 9 days after vaccination in both broiler and layer chickens, and lasts for life.

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

### **How does Ultifend ND IBD work?**

Ultifend ND IBD contains a type of turkey herpesvirus that does not cause disease in chickens but 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 Ultifend ND IBD is given to chickens, the animals' immune system (the body's natural defences) recognises the virus proteins as 'foreign' and makes antibodies against them. 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 Ultifend ND IBD have been shown in studies?**

Laboratory and field studies confirmed that Ultifend ND IBD stimulates active immunity in one-day-old chicks or 18-day-old chicken embryonated eggs to reduce death, clinical signs and lesions caused by ND virus and to reduce virus shedding; to reduce death, clinical signs and bursa lesions caused by very virulent IBD virus ; and to reduce death, clinical signs and lesions caused by classical MD virus.

Twenty-five laboratory studies were performed to demonstrate the efficacy of Ultifend ND IBD. Both routes of administration, i.e. injection under the skin or into embryonated eggs, were used for vaccination in these studies.

In laboratory studies to assess the onset of immunity, vaccinated chickens were challenged (brought in contact with the field viruses) to show the following levels of protection after vaccination:

- For MD, the level of protection after challenge was 93.9% in birds after vaccination into embryonated eggs and 88.9% for birds vaccinated by injection under the skin.
- For ND, the level of protection after challenge was 90% in birds after vaccination into embryonated eggs and 100% for birds vaccinated by injection under the skin.
- For IBD, the level of protection after challenge was 92% in birds after vaccination into embryonated eggs and 96% for birds vaccinated by injection under the skin.

Efficacy field trials confirmed the levels of protection after challenge with ND virus or IBD virus. No field study was presented for MD. However, the vaccine is considered effective against MD based on field studies showing that the modified virus produced proteins that were effective in protecting against ND and IBD. In addition, the efficacy against MD has been adequately demonstrated in laboratory trials.

### **What are the risks associated with Ultifend ND IBD?**

No side effects have been observed after vaccination with Ultifend ND IBD.

Vaccinated chickens may excrete the vaccine strain up to 49 days after vaccination. During this time, the contact of immunosuppressed chickens (with an impaired immune system) and unvaccinated chickens with vaccinated chickens should be avoided. The vaccine strain may spread to turkeys and, although the vaccine strain is not harmful to turkeys, its spread to turkeys should be avoided.

## **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 Ultifend 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 vaccinated with Ultifend ND IBD is 'zero' days, which means that there is no mandatory waiting time.

## **Why is Ultifend ND IBD authorised in the EU?**

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

## **Other information about Ultifend ND IBD**

Ultifend ND IBD received a marketing authorisation valid throughout the EU on 20-04-2021.

Further information on Ultifend ND IBD can be found on the Agency's website:  
[ema.europa.eu/medicines/veterinary/EPAR/ultifend-nd-ibd](http://ema.europa.eu/medicines/veterinary/EPAR/ultifend-nd-ibd).

This overview was last updated in 06-2021.