1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB+ND+EDS emulsion for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml dose contains:

Active substances:
Avian infectious bronchitis virus, type Massachusetts, strain M41, inactivated ≥ 6.0 $\log_2$ HI* units
Newcastle disease virus, strain Clone 30, inactivated ≥ 4.0 $\log_2$ HI* units per 1/50th dose or
≥ 50 PD_{50}** units per dose
Eggdrop syndrome 1976 virus, strain BC14, inactivated ≥ 6.5 $\log_2$ HI* units

* HI = haemagglutination inhibition.
** PD_{50} = 50% protective dose.

Adjuvant:
Liquid paraffin 215 mg

Excipients:

Qualitative composition of excipients and other constituents
Polysorbate 80
Sorbitan oleate
Glycine
Water for injections

Homogenous white to nearly white oily emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (breeders and layers).

3.2 Indications for use for each target species

The vaccine is recommended for the vaccination of laying and breeding birds to:
- Prevent egg production losses caused by infection with the Massachusetts serotype of avian infectious bronchitis virus (IBV) and reduce infection in primed birds.
- Prevent mortality and clinical signs and reduction of infection caused by Newcastle disease virus (NDV).
- Prevent egg production losses and egg quality defects caused by infection with eggdrop syndrome ‘76 virus (EDSV).

Onset of immunity: Active immunity develops within 4 weeks.

Duration of immunity: One laying period (for avian infectious bronchitis and Newcastle disease

viruses, this requires birds to have been adequately primed with live vaccines against these pathogens during the growing phase).

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system. Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration. Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress. Under certain conditions, for example extreme disease pressure, fully immune birds may succumb to disease. Therefore, successful vaccination may not be synonymous with full protection in the face of a disease challenge.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens (breeders and layers):

Very common (>1 animal / 10 animals treated):	Injection site swelling[1].

[1] Mild, may be observed at the injection site for 2 weeks.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Nobilis TRT inac, an Intervet inactivated vaccine containing TRT antigen strain But1#8544 (subgroup A).
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

3.9 Administration routes and dosage

Intramuscular or subcutaneous use.

Dose: 0.5 ml per bird.

Intramuscular injection in the thigh or chest muscle, or by subcutaneous injection in the back of the neck, using a medium sized needle (20 G x ½").
The veterinary medicinal product should be given to birds around 14 – 20 weeks of age but not less than 4 weeks before the expected start of lay.
Priming with live vaccines for avian infectious bronchitis and Newcastle disease viruses is necessary unless serological tests indicate otherwise. The interval between priming and booster should not be less than 4 weeks and preferably more than 6 weeks.

Allow the vaccine to reach ambient temperature (15 – 25 °C) before use.
The vaccine may occasionally separate into two layers on storage. This in no way affects its potency. Shake the bottle vigorously before and periodically during use.
An automatic injection system, incorporating a means to prevent back-flushing and hence possible contamination of the vaccine, should be used for administration.
Ensure that vaccination equipment is clean and sterile before use. Do not use vaccination equipment with rubber parts as the excipient may attack certain types of rubber.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

After administration of a two-fold overdose the reactions are not different from those observed after a single dose.
No effects other than those described in section 3.6.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AA13.

To stimulate active immunity against avian infectious bronchitis, Newcastle disease and eggdrop syndrome ’76 viruses.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 3 hours.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Cardboard box containing a PET bottle with 500 ml (1 000 doses) of the vaccine.
The bottles are closed with a nitryl rubber stopper and sealed with a coded aluminium cap.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/094/001

8. DATE OF FIRST AUTHORISATION

28/10/2005.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10/03/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary)