SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB+ND+EDS emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of 0.5 ml contains:

Active substances:

Inactivated avian infectious bronchitis virus, strain M41	$\geq$ 6.0 $\log_2$ HI units
Inactivated Newcastle disease virus, strain Clone 30	$\geq$ 4 $\log_2$ HI units per $^1/_{50}$ dose or $\geq$ 50 PD_{50} units per dose
Inactivated egg drop syndrome virus, strain BC14	$\geq$ 6.5 $\log_2$ HI units

Adjuvant:

Liquid paraffin	215 mg.

Excipients

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (breeders and layers).

4.2 Indications for use specifying the 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 egg drop 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).

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy birds 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. Immuno-competence 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.

4.5 Special precautions for use

Special precautions for the use in animals
None.

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 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 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 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.

4.6 Adverse reactions (frequency and seriousness)

A mild transient swelling may be observed at the injection site for 2 weeks.

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay or within 4 weeks before the onset of the laying period.

4.8 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 decided on a case-by-case basis.

4.9 Amounts to be administered and administration route

Dose: 0.5 ml per bird.
Routes of administration: 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").

Nobilis IB+ND+EDS should be given to birds around 14–20 weeks of age but not less than 4 weeks before the expected onset 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.

4.10 Overdose (symptoms, emergency procedures, antidotes) if necessary

No particular symptoms are observed after administration of a double dose.
No effects other than those described in section 4.6.

4.11 Withdrawal periods

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Aves, domestic fowl, inactivated viral vaccines.
ATCvet code: QI01AA13.

To stimulate active immunity against avian infectious bronchitis, Newcastle disease and egg drop syndrome '76 viruses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light liquid paraffin
Polysorbate 80
Sorbitan oleate
Glycine
Formaldehyde
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 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.

6.4 Special precautions for storage

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

6.5 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 nitrile rubber stopper and sealed with a coded aluminium cap.

6.6 Special precautions for disposal of unused veterinary medicinal product or waste material derived from the use of such products

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4132

9. DATE OF FIRST AUTHORISATION

19 October 2005

10. DATE OF REVISION OF THE TEXT

January 2025

Gavin Hall

Approved: 03 January 2025