

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IB_{multi}+ND+EDS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION OF PRODUCT

Active ingredient	per dose
Inactivated antigens:	
Infectious Bronchitis M41	≥ 5.5 log ₂ VN units
Infectious Bronchitis D274	≥ 4.0 log ₂ VN units
Egg Drop Syndrome	≥ 6.5 log ₂ HI units
Newcastle Disease	≥ 4 log ₂ HI units per 1/50 th dose or ≥ 50 PD ₅₀ units per dose as per Ph.Eur. as measured in respective potency tests
Excipients	
Liquid paraffin	215 mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens, future layers and breeders.

4.2 Indications for use

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 IBV, and reduce infection in primed birds.
- Reduce egg production losses and egg shell quality defects caused by infection with the D274 serotype of IBV.
- Prevent mortality and clinical signs caused by Newcastle disease.
- Prevent egg production losses and egg quality defects caused by infection with Egg Drop Syndrome Virus.
- Active immunity develops within 4 weeks and lasts at least one laying period (for Infectious Bronchitis and Newcastle disease this requires birds to have been adequately primed with live vaccines during the growing phase).

4.3 Contra-indications

Not to be used during lay or within 4 weeks before onset of lay.

4.4 Special warnings for each target species

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 use in animals

Only healthy birds should be vaccinated.

Special precautions to be taken by the person administering the product to animals

To the user

This 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 and 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 product contains mineral oil. Even if very tiny amounts have been injected, accidental injection with this oil-based product can cause intense swelling which may for example result in ischaemic necrosis and 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 effects (frequency and seriousness)

A slight swelling may be felt at the site of vaccination.

4.7 Use during pregnancy, lactation or lay

No safety or efficacy data has been produced for birds in lay, hence Nobilis IB_{multi}+ND+EDS must not be used in chickens during lay or within 4 weeks before onset of lay.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and/or efficacy data are available which demonstrate that this vaccine can be administered the same day but not mixed with other Intervet inactivated vaccines containing RT or Reo antigens given at the same time but at separate sites.

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

Nobilis IB_{multi}+ND+EDS should be given to birds around 16 - 20 weeks of age but not less than 4 weeks before the expected onset of lay.

Priming with live vaccines for Infectious Bronchitis and Newcastle Disease 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.

Each bird should be given 0.5 ml of vaccine intramuscularly in the thigh muscle or subcutaneously into the back of the neck, using a medium sized needle (20 g x ½"). 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.

Allow the vaccine to reach ambient temperature (15 °C - 25 °C) before use. The vaccine may occasionally separate into two layers on storage. This in no way affects its potency, but it should be shaken vigorously before and during use to ensure a good emulsification.

4.10 Overdose

Similar effects to single dose were observed in birds vaccinated with a double dose of the vaccine.

4.11 Withdrawal periods

Zero days.

5. IMMUNOLOGICAL PROPERTIES

The vaccine contains inactivated Infectious Bronchitis M41 and D274, Newcastle Disease and Egg Drop Syndrome antigens. The antigens are inactivated with formaldehyde or β-Propiolactone and suspended in the aqueous phase of a water-in-oil adjuvant emulsion, in order to give a prolonged stimulation of immunity.

The vaccine stimulates active immunity against Infectious Bronchitis (Massachusetts and D274 serotypes), Newcastle Disease and Egg Drop Syndrome viruses.

An enhanced immune response is obtained when the product is used for booster immunisation after priming the birds with live vaccines against Infectious Bronchitis and Newcastle Disease. The best results will be obtained if vaccination with the inactivated vaccine takes place at least 4 weeks after administration of the live primer.

ATC Vet code QI01AA13

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light liquid paraffin, polysorbate, sorbitan oleate, glycine

6.2 Incompatibilities

Do not mix with other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale

- Glass bottles: 2 years

- PET bottles: 2 years

Shelf life after first opening of the immediate packaging: 3 hours

6.4 Special precautions for storage

Store in a refrigerator (2 °C - 8 °C). Do not freeze.

6.5 Nature and composition of the immediate packaging

Carton with one clear bottle of glass Type II or PET bottles containing 500 ml (1000 doses). The bottles are closed with a nitril 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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

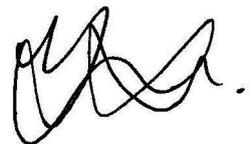
Vm 01708/4367

9. DATE OF FIRST AUTHORISATION

18 July 2003

10. DATE OF REVISION OF THE TEXT

December 2020



Approved: 02 December 2020