

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box/500 ml}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Nobilis IB+ ND+EDS

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Inactivated avian infectious bronchitis virus, strain M41	≥ 6.0 log <sub>2</sub> HI units
Inactivated Newcastle disease virus, strain Clone 30	≥ 4 log <sub>2</sub> HI units
	Per 1/50 dose or
	≥ 50 PD <sub>50</sub> units
Inactivated egg drop syndrome virus, strain BC14	≥ 6.5 log <sub>2</sub> HI units
Liquid paraffin (adjuvant)	215 mg

**3. PHARMACEUTICAL FORM**

Emulsion for injection.

**4. PACKAGE SIZE**

500 ml (1,000 doses).

**5. TARGET SPECIES**

Target species: Chickens (breeders and layers).

**6. INDICATION(S)**

Inactivated vaccine for active immunisation of laying and breeding birds against avian infectious bronchitis, Newcastle disease and egg drop syndrome '76.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Routes: 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").

**8. WITHDRAWAL PERIOD**

Withdrawal periods: Zero days.

**9. SPECIAL WARNING(S), IF NECESSARY**

## **10. EXPIRY DATE**

EXP end of: {month/year}

## **11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator.

Do not freeze.

Protect from light.

Keep the container in the outer carton.

Once broached, use within 3 hours.

## **12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

## **13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE**

*[Distribution category]*

For animal treatment only.

POM-VPS

## **14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

## **15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

MA holder in the UK:

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

MK7 7AJ, UK

## **16. MARKETING AUTHORISATION NUMBER(S)**

Vm 01708/4275

## **17. MANUFACTURER’S BATCH NUMBER**

Lot: {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Label/500 ml}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Nobilis IB+ND+EDS

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

One dose of 0.5 ml contains: Inactivated avian infectious bronchitis virus  $\geq 6.0 \log_2$  HI units, inactivated Newcastle disease virus  $\geq 4 \log_2$  HI units per 1/50 dose, inactivated egg drop syndrome virus  $\geq 6.5 \log_2$  HI units and liquid paraffin (adjuvant) 215 mg.

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

500 ml (1,000 doses).

**4. ROUTE(S) OF ADMINISTRATION**

Emulsion for injection.

**5. WITHDRAWAL PERIOD**

Withdrawal period: Zero days.

**6. BATCH NUMBER**

Lot: {number}

**7. EXPIRY DATE**

EXP end of: {month/year}

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

Inactivated vaccine for active immunisation of laying and breeding birds against avian infectious bronchitis, Newcastle disease and egg drop syndrome '76. Accidental self-injection is dangerous. For complete indications, dosage and administration advice, warnings, precautions and disposal advice: Read the package leaflet before use.

Target species: Chickens (breeders and layers). Routes: Intramuscular or subcutaneous injection.

Keep out of the sight and reach of children.

Store in a refrigerator. Do not freeze. Protect from light. Keep the container in the outer carton. Once broached, use within 3 hours. To be supplied only on veterinary prescription.

UK only  
Vm 01708/4275  
POM-VPS  
MSD Animal Health UK Ltd.  
Walton Manor  
Walton, Milton Keynes  
MK7 7AJ, UK

**PACKAGE LEAFLET FOR:**

**Nobilis IB+ND+EDS**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holders

UK only:

MSD Animal Health UK Ltd.  
Walton Manor  
Walton  
Milton Keynes  
Buckinghamshire, MK7 7AJ, UK

Manufacturer responsible for batch release

Intervet International B.V.  
Wim de Körverstraat 35  
5831 AN Boxmeer  
The Netherlands

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Nobilis IB+ND+EDS  
Emulsion for injection

**3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS**

One dose of 0.5 ml contains:

Inactivated avian infectious bronchitis virus, strain M41	≥ 6.0 log <sub>2</sub> HI units
Inactivated Newcastle disease virus, strain Clone 30	≥ 4 log <sub>2</sub> HI units per 1/50 dose or ≥ 50 PD <sub>50</sub> units per dose
Inactivated egg drop syndrome virus, strain BC14	≥ 6.5 log <sub>2</sub> HI units
Liquid paraffin (adjuvant)	215 mg

**4. INDICATION(S)**

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 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).

## **5. CONTRAINDICATIONS**

None.

## **6. ADVERSE REACTIONS**

A mild transient swelling may be observed at the injection site for 2 weeks. If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

## **7. TARGET SPECIES**

Chickens (breeders and layers).

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

Dose: 0.5 ml vaccine 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 virus and Newcastle disease virus 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.

## **9. ADVICE ON CORRECT ADMINISTRATION**

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.

## 10. WITHDRAWAL PERIOD(S)

Zero days.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Protect from light.

Keep the container in the outer carton.

Shelf life after first opening of the container: 3 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after 'EXP end of'.

## 12. SPECIAL WARNING(S)

### 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. 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.

### 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.

### Lay

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

### 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 Nobilis TRT inac, an MSD 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.

### Overdose (symptoms, emergency procedures, antidotes)

No particular symptoms are observed after administration of a double dose.

No effects other than those described in section 6.

### Incompatibilities

Do not mix with any other veterinary medicinal product.

## **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

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

## **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

February 2021

## **15. OTHER INFORMATION**

For animal treatment only.

To be supplied only on veterinary prescription.

Pharmacotherapeutic group: Immunologicals for Aves; domestic fowl, inactivated viral vaccines ATC vet code: QI01AA13.

To stimulate active immunity against avian infectious bronchitis (Massachusetts serotype), Newcastle disease and egg drop syndrome viruses.

Pack size: 500 ml (1,000 doses).

UK only

Vm 01708/4275

POM-VPS

To be supplied only on veterinary prescription.

Distributor in Northern Ireland

Intervet Ireland Ltd.

Magna Drive, Magna Business Park

Citywest Road, Dublin 24, Ireland

Revised: February 2021  
AN: 01606/2020

Approved 12 February 2021

A handwritten signature in black ink, consisting of a stylized, cursive initial followed by the name "Hunter." with a period.