

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

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

Nobilis IBmulti+ND+EDS

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

Per dose of 0.5 ml:

Inactivated antigens of

Infectious Bronchitis M41  $\geq 5.5 \log_2$  VN units

Infectious Bronchitis D274  $\geq 4.0 \log_2$  VN units

Egg Drop Syndrome  $\geq 6.5 \log_2$  HI units

Newcastle Disease  $\geq 4 \log_2$  HI units per 1/50<sup>th</sup> dose or  
 $\geq 50 \text{ PD}_{50}$  units per dose as per Ph.Eur.  
as measured in respective potency tests

Liquid paraffin (adjuvant) 215 mg

**3. PHARMACEUTICAL FORM**

Emulsion for injection.

**4. PACKAGE SIZE**

500 ml (1000 doses).

**5. TARGET SPECIES**

Target species: Chickens (breeders and future layers).

**6. INDICATION(S)**

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

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

Route: Intramuscular injection in the thigh muscle or subcutaneous injection in the back of the neck.

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Withdrawal period: Zero days.

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

Do not use after the expiry date printed on the carton/label.

### Operator warnings:

To the user: This 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 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 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.

## 10. EXPIRY DATE

EXP end of: {month/year}

## 11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2 °C - 8 °C).

Do not freeze.

Once broached, use within 3 hours.

Keep the container in the outer carton.

## 12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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

*[Distribution category]*

For animal treatment only.

POM-V

**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:

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

MK7 7AJ

Distributor in Northern Ireland

Intervet Ireland Ltd.

Magna Drive

Magna Business Park

Citywest Road

Dublin 24

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

Vm 01708/4367

**17. MANUFACTURER’S BATCH NUMBER**

Batch: {number}

Do not use after the expiry date printed on the carton/label.

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

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

Nobilis IBmulti+ND+EDS

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

Per dose of 0.5 ml:

Inactivated antigens of Infectious Bronchitis M41:  $\geq 5.5 \log_2$  VN units; Infectious Bronchitis D274:  $\geq 4.0 \log_2$  VN units; Egg Drop Syndrome  $\geq 6.5 \log_2$  HI units;

Newcastle Disease:  $\geq 4 \log_2$  HI units per 1/50<sup>th</sup> dose or  $\geq 50$  PD<sub>50</sub> units per dose as per Ph.Eur. as measured in respective potency tests

Liquid paraffin (adjuvant) 215 mg.

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

500 ml (1000 doses).

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

Emulsion for injection.

**5. WITHDRAWAL PERIOD**

Withdrawal period: Zero days.

**6. BATCH NUMBER**

Batch: {number}

**7. EXPIRY DATE**

EXP end of: {month/year}

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

Target species: Chickens (breeders and future layers)

Route: IM or SC.

Accidental self injection is dangerous.

Read the package leaflet before use.

Store at 2 °C - 8 °C. Do not freeze.

Once broached, use within 3 hours.

Keep the container in the outer carton.

For animal treatment only.

Keep out of the sight and reach of children.

POM-V

Vm 01708/4367

**PACKAGE LEAFLET FOR:**  
Nobilis IBmulti+ND+EDS

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

**Manufacturing Authorisation holder:**

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

**Manufacture Authorisation holder 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 IBmulti+ND+EDS

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

Active ingredients per dose of 0.5 ml:

Inactivated antigens of:

Infectious Bronchitis M41	≥ 5.5 log <sub>2</sub> VN units
Infectious Bronchitis D274	≥ 4.0 log <sub>2</sub> VN units
Egg Drop Syndrome	≥ 6.5 log <sub>2</sub> HI units
Newcastle Disease	≥ 4 log <sub>2</sub> HI units per 1/50 <sup>th</sup> dose or ≥ 50 PD50 units per dose as per Ph.Eur. as measured in respective potency tests
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 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).

## **5. CONTRAINDICATIONS**

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

## **6. ADVERSE REACTIONS**

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

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## **7. TARGET SPECIES**

Chickens (breeders and future layers).

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

Nobilis IBmulti+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.

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

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.

## **10. WITHDRAWAL PERIOD(S)**

Zero days.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C - 8 °C).

Do not freeze.

Protect from light.

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

Keep container in the outer carton.

Do not use after the expiry date stated on the label.

## 12. SPECIAL WARNING(S)

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 for the 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 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 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 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.

### **Use during lay**

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

### **Interactions**

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.

### **Incompatibilities**

Do not mix with any other veterinary medicinal product.

### **Overdose**

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

## **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**

December 2020.

## **15. OTHER INFORMATION**

Pharmacotherapeutic group: Immunologicals for aves, domestic fowl, inactivated viral vaccines, newcastle disease virus / paramyxovirus + avian infectious bronchitis virus + avian adenovirus.

ATC vet code: QI01AA13.

To stimulate active immunity against Infectious Bronchitis (Massachusetts and D274 serotypes), Newcastle Disease and Egg Drop Syndrome viruses.

For animal treatment only.

### **Pack size**

Cardboard box containing a clear glass type II or PET bottle with 500 ml (1000 doses).

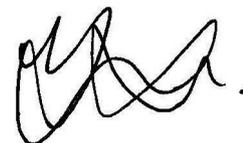
The bottles are closed with a nitrile rubber stopper and sealed with a coded aluminium cap.

Vm 01708/4367

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

A handwritten signature in black ink, consisting of several loops and a final flourish.

Approved: 02 December 2020