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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Reo+IB+G+ND

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 0.5 ml dose contains inactivated antigens of:

Reo virus (strains 1733 & 2408)	inducing ≥ 7.4 $\log_2$ ELISA units
Infectious Bronchitis virus (strain M41)	inducing ≥ 6.0 $\log_2$ HI units
Gumboro virus (strain D78)	inducing ≥ 14.5 $\log_2$ VN units
Newcastle Disease virus (strain Clone 30)	inducing ≥ 4.0 $\log_2$ HI units per 1/50th dose or containing ≥ 50 PD50 units
Liquid paraffin:	215 mg

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

500 ml (1000 doses).

5. TARGET SPECIES

Target species: Chickens (breeding birds).

6. INDICATION(S)

To stimulate active immunity against the Massachusetts serotypes of Infectious Bronchitis virus, against Newcastle disease, and to stimulate active immunity against Reo virus and Infectious Bursal (Gumboro) disease in order to provide passive immunity to the progeny.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Route: IM or SC injection.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

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 further medical advice.
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 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 and transport at 2 °C - 8°C.
Protect from light.
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

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

Distributor Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4332

17. MANUFACTURER’S BATCH NUMBER

Batch: {number}

To be supplied only on veterinary prescription.
Read the package leaflet before use.

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Reo+IB+G+ND

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 0.5 ml dose contains:
Inactivaced antigens of
Reo virus (strains 1733 & 2408) inducing 7.4 log2 ELISA units
IB virus (strain M41) inducing 6.0 log2 HI units
Gumboro virus (strain D78) inducing 14.5 log2 VN units
ND virus (strain Clone 30) inducing 4.0 log2 HI units per 1/50th dose or containing 50 PD50 units
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

Route: IM or SC 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”

For animal treatment only.
Target species: Chickens.
Accidental injection is dangerous.
Read the package leaflet before use. Store and transport at 2 °C - 8°C. Do not freeze. Protect from light. In-use shelf life: 3 hours. Keep container in the outer carton.

MA Holder:

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

POM-V
To be supplied only on veterinary prescription.
Vm 01708/4332
Keep out of the sight and reach of children.
Emulsion for injection.

PACKAGE LEAFLET FOR:

Nobilis Reo+IB+G+ND
Emulsion for injection

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

Marketing authorisation holder:

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

Manufacturer responsible for the batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis Reo+IB+G+ND
Emulsion for injection

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

Active ingredient	**per dose of 0.5 ml**
Reo virus strains 1733 & 2408	inducing ≥ 7.4 $\log_2$ ELISA units
Infectious Bursitis virus strain M41	inducing ≥ 6.0 $\log_2$ HI units
Infectious Bursal (Gumboro) virus strain D78	inducing ≥14.5 $\log_2$ VN units
Newcastle Disease Virus strain Clone 30	inducing ≥ 4.0 $\log_2$ HI units per 1/50th dose or containing ≥ 50 PD_{50} units
Adjuvant	
Liquid paraffin	215 mg

4. INDICATION(S)

Active immunisation of breeder chickens for
• prevention of egg drop caused by the Massachusetts serotype of Infectious Bronchitis virus;
• prevention of mortality and clinical signs caused by Newcastle Disease virus;

• passive immunisation of the progeny of the vaccinated birds against Infectious Bursal Disease for at least the first four weeks;
• passive immunisation of the progeny of the vaccinated birds against Reo virus for production during the susceptible period in the early phase of life up to 7 days of age.
Onset of immunity: 4 weeks
Duration of immunity: one laying period.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A slight transient swelling (resolved within 3 weeks) may be felt in 50 % of the vaccinated birds at the site of vaccination.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens (Breeding birds).

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

Each bird should be given 0.5 ml of vaccine intramuscularly in the thigh or chest muscle or subcutaneously into the lower part of the neck.
The product 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, Newcastle Disease and Gumboro disease is necessary unless serological tests indicate otherwise. The interval between priming and boosting should be more than 4 weeks and less than 6 weeks.
For an optimal response to the Reovirus component in birds not primed by field virus two vaccinations should be given approximately 6 weeks apart.

9. ADVICE ON CORRECT ADMINISTRATION

Allow the vaccine to reach ambient temperature (15 °C - 25 °C) before use. Shake 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 to administer the vaccine. 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 and transport at 2 °C - 8 °C. Do not freeze. Protect from light.
Shelf life after first opening: 3 hours.
Keep the container in the outer carton.
Do not use after the expiry date stated on the label and carton.

12. SPECIAL WARNING(S)

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 further medical advice.

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 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

Do not use in birds in lay. Not to be used within 4 weeks before the onset of lay.

Interactions

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Intervet's inactivated oil emulsion vaccines, containing the TRT or EDS antigen, administered 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 products 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.

Overdose
No other reactions than those after a single dose administration are expected.
Incompatibilities
Do not mix with any other veterinary medicinal product.

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

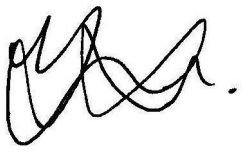
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2020

15. OTHER INFORMATION

For animal treatment only.
Pack size
Carton containing one glass bottles (type II Ph.Eur) or one PET bottle with 500 ml (1000 doses).
MA number
Vm 01708/4332
Legal category
POM-V
To be supplied only on veterinary prescription.
Distributor Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24



Approved: 03 July 2020