

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis RT+IBmulti+G+ND
Emulsion for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 0.5 ml:

ART strain But1#8544 :	inducing	$\geq 9.5 \log_2$ ELISA units
IBV strain M41(Massachusetts):	inducing	$\geq 5.5 \log_2$ VN units
IBV strain 249g (D274/D207):	inducing	$\geq 4.0 \log_2$ VN units
IBDV strain D78:	inducing	$\geq 14.5 \log_2$ VN units
NDV strain Clone 30:	inducing	$\geq 4.0 \log_2$ HI units per 1/50 th dose or containing ≥ 50 PD ₅₀ units

Adjuvant: liquid paraffin

3. PHARMACEUTICAL FORM

Emulsion for injection (water-in-oil)

4. PACKAGE SIZE

500/1000 doses

5. TARGET SPECIES

Breeder chickens

6. INDICATION(S)

Vaccine against Infectious Bronchitis (Massachusetts and D274/D207), Newcastle Disease, Avian Rhinotracheitis and Gumboro Disease.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular injection.
Shake well, allow to reach ambient temperature, use sterile equipment without rubber parts.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous – see package leaflet before use.

10. EXPIRY DATE

Exp. {month/year}
Once broached, use within 3 hours

11. SPECIAL STORAGE CONDITIONS

Store at 2°C -8°C. Protect from light. Do not freeze.

12. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose by appropriate channels.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only – to be supplied only on veterinary prescription..
[can be replaced by national abbreviation or symbol]

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

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. NUMBER(S) IN THE REGISTER OF MEDICINAL PRODUCTS

Vm 01708/4627

17. MANUFACTURER'S BATCH NUMBER

{number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Nobilis RT+IBmulti+G+ND

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

Marketing authorisation holder and manufacturer:

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

2 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis RT+IBmulti+G+ND
Emulsion for injection

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

Per dose of 0.5 ml

ART strain But1#8544 :	inducing	$\geq 9.5 \log_2$ ELISA units*
IBV strain M41(Massachusetts):	inducing	$\geq 5.5 \log_2$ VN units*
IBV strain 249g (D274/D207):	inducing	$\geq 4.0 \log_2$ VN units*
IBDV strain D78:	inducing	$\geq 14.5 \log_2$ VN units*
NDV strain Clone 30:	inducing	$\geq 4.0 \log_2$ HI units per 1/50 th dose* or containing ≥ 50 PD ₅₀ units

* serological response in chickens

Adjuvant: liquid paraffin

4. INDICATION(S)

Active immunisation of breeder chickens for:

- reduction of infection and prevention of egg drop caused by the Massachusetts serotype of Infectious Bronchitis virus;
- reduction of egg drop and egg shell defects caused by the D274/D207 serotype of Infectious Bronchitis virus;
- reduction of infection caused by Newcastle Disease virus;
- prevention of respiratory signs and reduction of egg drop and egg shell defects related to Avian Rhinotracheitis virus;
- passive immunisation of the progeny of the vaccinated birds against Infectious Bursal Disease for at least the first four weeks of life.

For Infectious Bronchitis, Newcastle and Avian Rhinotracheitis virus:

Onset of immunity: 4 weeks after vaccination
Duration of immunity: one laying period.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

A mild transient swelling may be observed at the injection site for 2 weeks.
After administration of a double dose the reactions are not different from those observed after a single dose.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Breeder chickens

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

Administer one dose of 0.5 ml vaccine per bird via intramuscular injection in the thigh or chest muscle.

Nobilis RT+IBmulti+G+ND should be given to birds around 14-20 weeks of age but not later than 4 weeks before the expected onset of lay.

In the event that live vaccines were used to prime birds against Infectious Bronchitis, Rhinotracheitis, Newcastle Disease and Infectious Bursal Disease, Nobilis RT+IBmulti+G+ND should be given at least 4 weeks after the administration of the live vaccines.

9. ADVICE ON CORRECT ADMINISTRATION

Allow vaccine to reach ambient temperature (15-25°C) before use.

Shake the bottle vigorously before use and periodically during use.

Ensure that vaccination equipment is clean and sterile before use.

Do not use vaccination equipment with rubber parts as the excipient may damage certain types of rubber.

Do not mix with other vaccines.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach and sight of children.

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

Do not use after the expiry date which is stated on the label
Once broached, use within 3 hours.

12. SPECIAL WARNING(S)

Vaccinate only healthy animals. Do not use during lay or within 4 weeks before the onset of the laying period.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product needs to be made on a case by case basis.

Do not mix with any other veterinary medicinal product.

Special precautions to be taken by the person administering the medicinal 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 insert 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.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2020

15. OTHER INFORMATION

Nobilis RT+IBmulti+G+ND is an inactivated viral vaccine against Infectious Bronchitis (Massachusetts and D274/D207), Newcastle Disease, Avian Rhinotracheitis and Gumboro Disease .

The vaccine contains an oil adjuvant.

ATC-vet code: QI01AA06.

Presentations:

Vial of 250 ml (500 doses) or 500 ml (1000 doses)

Not all pack sizes may be marketed.

For animal treatment only.

For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.

A handwritten signature in black ink, consisting of several vertical strokes followed by a horizontal line that curves upwards to the right.

Approved 17 November 2020