PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis RT Inac
Emulsion for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 0.5 ml:
Active substance:
Inactivated ARTV (strain But1#8544) subtype A inducing $\geq$ 10 $\log_2$ ELISA units

Adjuvant: Liquid paraffin 215 mg

3. PHARMACEUTICAL FORM

Emulsion (water-in-oil) for injection [*only mentioned once*]

4. PACKAGE SIZE

250 ml and 500 ml vials

5. TARGET SPECIES

Chickens and turkeys (future layers and breeders)

6. INDICATION(S)

Active immunisation against Avian Rhinotracheitis virus

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular injection

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

This is a water-in-oil emulsion. Accidental self injection is dangerous, please follow instructions in leaflet.

10. EXPIRY DATE

Exp. month/year:

11. SPECIAL STORAGE CONDITIONS

Store dark at 2° - 8°C. Do not freeze.
Broached vials should be used immediately after opening.

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

Read the package leaflet before use (only mentioned once).

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only
To be supplied only on veterinary prescription *[can be replaced by national text, abbreviation or symbol]*

14. THE WORDS "KEEP OUT OF 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. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4629

17. MANUFACTURER'S BATCH NUMBER

Batch / Lot: …

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGE (short version)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis RT inac [*or national name*]

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Per dose of 0.5ml:
ART virus strain But1#8544 inducing ≥ 10 $\log_2$ ELISA units

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

250 ml, 500 ml

4. ROUTE OF ADMINISTRATION

I.m. injection

5. WITHDRAWAL PERIOD

withdrawal period:
Zero days

6. BATCH NUMBER

Batch/lot:

7. EXPIRY DATE

Exp: …

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (long version)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis RT inac [*or national name*]
Emulsion for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 0.5 ml:
ART virus strain But1#8544: inducing $\geq$ 10 $\log_2$ ELISA units

3. PHARMACEUTICAL FORM

Emulsion for injection [*only mentioned once*]

4. PACKAGE SIZE

250 ml and 500 ml vials

5. TARGET SPECIES

Chickens and turkeys

6. INDICATION(S)

Vaccine against Avian Rhinotracheitis virus

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use [*only mentioned once*].
I.M. injection

8. WITHDRAWAL PERIOD

Withdrawal period:
Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Self-injection is dangerous, please follow instructions in leaflet.

10. EXPIRY DATE

Exp. month/year:

11. SPECIAL STORAGE CONDITIONS

Store dark at 2° - 8°C. Do not freeze.
Use broached vials immediately.

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

Read the package leaflet before use [*only mentioned once*].

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only
To be supplied only on veterinary prescription *[can be replaced by national text, abbreviation or symbol]*

14. THE WORDS "KEEP OUT OF 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. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4629

17. MANUFACTURER'S BATCH NUMBER

Batch / Lot: …

PACKAGE LEAFLET

Nobilis RT Inac
[*or national name*]

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

Manufacturer 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 RT inac [*or national name*]
Emulsion for injection

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

Per dose of 0.5 ml:
Active substance:
Inactivated ARTV (strain But1#8544) subtype A inducing $\geq$ 10 $\log_2$ ELISA units

Adjuvant: Liquid paraffin 215 mg

4. INDICATION(S)

Active immunisation of chickens to reduce clinical signs, including egg-drop, of Swollen Head Syndrome due to infection with Avian pneumovirus. Active immunisation of turkeys to reduce clinical signs due to infection with Turkey Rhinotracheitis virus.
The onset of immunity is 3 weeks and the duration of immunity is one laying period.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

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 leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens and turkeys (future layers and breeders).

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

The following dosage regimen should be used:
Chickens: one dose of 0.5 ml per bird by intramuscular injection into the chest muscle. A single dose should be administered at approximately 14-20 weeks, but no later than 4 weeks before the expected onset of lay. In the event that live vaccines were used to prime birds against Avian Rhinotracheitis, Nobilis RT inac should be given at least 4 weeks after the administration of the live vaccine.

Turkeys: one dose of 0.5 ml per bird by intramuscular injection in the chest muscle. A single dose should be administered at approximately 28 weeks of age, but no later than 4 weeks before the expected onset of lay. The vaccine should be administered only to birds that have been vaccinated with the live Nobilis TRT vaccine as a primary vaccination (administered by nebulisation or oculonasal route from one day of age onwards).

9. ADVICE ON CORRECT ADMINISTRATION

Before use, allow the vaccine to reach room temperature (5-25˚C).
Shake vigorously before and during use.
Use sterile vaccination equipment.
Do not use vaccination equipment, which has rubber parts, since the excipient may damage certain types of rubber.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Store in refrigerator (2°C - 8°C).
Do not freeze.
Protect from light.
Broached vials should be used immediately after opening.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Vaccinate only healthy animals.

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

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with other inactivated Intervet vaccines containing the IBV strain M41, IBV strain D274, IBDV, ND and EDS antigens in chickens and other inactivated Intervet vaccines containing the ND antigen in turkeys. In the case of products administered parentally, the products should be given at different 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 decided on as case by case basis.

Do not mix with any other vaccine or immunological product.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
To the user:
This product contains mineral oil. Accidental injection (self infection) 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, results 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 REVISED

November 2020

15. OTHER INFORMATION

ATC vet code: QI01AA17
Inactivated viral vaccine

For animal treatment only
National requirements on distribution channel, if any.

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

Approved 17 November 2020