LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis RT inac emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.5 ml dose contains:

Active substance:
Inactivated AMPV (strain But1#8544) subtype A inducing ≥ 10 $\log_2$ ELISA units

3. PACKAGE SIZE

250 ml (500 doses)
500 ml (1000 doses)

4. TARGET SPECIES

Chickens and turkeys

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator. Do not freeze. Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/3035

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL PET BOTTLE (250 ml, 500 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis RT inac emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

500 doses
1000 doses

Each 0.5 ml dose contains:
Inactivated AMP virus strain But1#8544: inducing ≥ 10 $\log_2$ ELISA units

3. TARGET SPECIES

Chickens and turkeys

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator. Do not freeze. Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

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

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Nobilis RT inac emulsion for injection for chickens and turkeys

2. Composition

Each 0.5 ml dose contains:

Active substance:
Inactivated avian metapneumovirus (strain But1#8544) subtype A
inducing ≥ 10 $\log_2$ ELISA units*

*serological response in chickens

Adjuvant:
Light liquid paraffin: 215 mg

White to nearly white oily emulsion.

3. Target species

Chickens and turkeys.

4. Indications for use

Active immunisation of chickens to reduce clinical signs of Swollen Head Syndrome, including egg-drop;and to reduce clinical signs of turkey rhinotracheitis in turkeys. Both are caused by avian metapneumovirus.

Onset of immunity: 3 weeks post-vaccination.
Duration of immunity: one laying period.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Not applicable.

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 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 veterinary medicinal 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 veterinary medicinal 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.

Special precautions for the protection of the environment:
Not applicable.

Laying birds:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with other inactivated Nobilis vaccines containing the IBV strain M41, IBV strain D274, IBDV, ND and EDS antigens in chickens and other inactivated Nobilis vaccines containing the ND antigen in turkeys. In the case of products administered parentally, the vaccines 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.

Overdose:
No adverse effects, other than the one mentioned under the heading "Adverse events", have been reported after administering a double dose of the vaccine.

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State’s competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Chickens and turkeys:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1].

[1] Mild, lasting up to 2 weeks.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

The following dosage regimen should be used:
Chickens:
One dose of 0.5 ml per chicken 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. If live vaccines were used to prime chickens 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 turkey 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 turkeys 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

Allow the vaccine to reach room temperature (15 °C - 25 °C) before use.
Shake the bottle vigorously before 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.

10. Withdrawal periods

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: use immediately.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

FOR UK(NI) ONLY:
Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon <or pharmacist> how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 01708/3035

Pack sizes:
Cardboard box with one bottle of 250 ml (500 doses) or 500 ml (1000 doses).
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:
MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ

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

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

<Local representatives <and contact details to report suspected adverse reactions>:>
MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

17. Other information

Nobilis RT inac vaccine contains the But 1 #8544 (subtype A) strain of the avian metapneumovirus. The virus is inactivated with beta-propiolactone and incorporated into the aqueous phase of a water-in-oil emulsion in order to enhance a prolonged stimulation of the immune system in the target species (chickens and turkeys). The active ingredient stimulates immunity against Turkey Rhinotracheitis (TRT) in turkeys and Swollen Head Syndrome (SHS) in chickens, both caused by avian metapneumovirus.

An enhanced immune response is obtained when the product is used for booster immunisation after priming the birds with live vaccines, if available, against Avian Rhinotracheitis. The best results will be obtained if vaccination with the inactivated vaccine takes place at least 4 weeks after administration of the live primer.

Any additional information concerning distribution, possession or any necessary precaution in conformity with the marketing authorisation and in accordance with article 14(2) and/or national requirements may appear in this rectangle

Gavin Hall
Approved: 22 June 2024