1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis TRT inac emulsion for injection for chickens and turkeys

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml dose contains:

Active substance:
Inactivated avian metapneumovirus virus, strain But 1 #8544: $\geq 10 \log_2$ ELISA units*

*serological response in chickens

Adjuvant:
Light liquid paraffin: 215 mg

Excipients:

Qualitative composition of excipients and other constituents
Polysorbate 80
Sorbitan oleate
Glycine
Water for injections

White to nearly white oily emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Chickens and turkeys.

3.2 Indications for use for each target species

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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

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-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 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, 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.

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

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 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.

3.9 Administration routes and dosage

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 containing strain But 1 #8544 were used to prime chickens against Avian Rhinotracheitis, the vaccine 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. This vaccine should be administered only to turkeys that have been primed with a live TRT vaccine containing strain But 1 #8544.

Before use, allow the vaccine to reach room temperature (15 °C - 25 ºC).
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AA17.

Nobilis TRT 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Store in a refrigerator (2 ºC – 8 ºC).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Bottle of polyethylene terephthalate (PET), closed with a nitryl rubber stopper and sealed with a colour coded aluminium cap..

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

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/180/001

8. DATE OF FIRST AUTHORISATION

28/05/2004

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

22/02/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).