1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis RT inac (AT, BE, DE, DK, EL, ES, FI, IT, NL, LU, PT)
FR: Nobilis RTV inac
IE, UK: Nobilis TRT inac

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per 0.5 ml dose:

Active substance:	
Inactivated Avian rhinotracheitis virus, strain But 1 #8544:	$\geq 10 \log_2$ ELISA units*
Adjuvant: liquid paraffin:	215 mg

*serological response in chickens

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White to nearly white oily emulsion for injection

4. CLINICAL PARTICULARS

4.1 Target species

Chickens and turkeys (future layers and breeders).

4.2 Indication for use, specifying the target species

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.

4.3 Contraindications

None

4.4 Special warnings

None.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate only healthy animals.

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 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, 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.

4.6 Adverse reactions (frequency and seriousness)

Mild transient swelling may be observed at the injection site for 2 weeks.

4.7 Use during pregnancy, lactation or lay

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

4.8 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 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.

4.9 Amounts to be administered and administration route

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 containing strain But 1 #8544 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. Nobilis RT inac should be administered only to birds that have been primed with a live TRT vaccine containing strain But 1 #8544.

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Nobilis RT inac vaccine contains the But 1 #8544 (subtype A) strain of the Avian rhinotracheitis virus. 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 pneumovirus.
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.

ATC Vet Code: QI01AA17.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light liquid paraffin
Polysorbate 80
Sorbitan oleate
Glycine
Water for injection

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf-life

24 months.
Use immediately after opening.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Box with a multidose polyethylene terephthalate (PET) vial of 250 ml or 500 ml closed with a nitryl rubber stopper.

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

represented by the national companies
in the Member States

8. MARKETING AUTHORISATION NUMBER(S):

FR: 11763

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:

16-12-2002

10. DATE OF REVISION OF THE TEXT:

16/10/2008

PROHIBITION OF SALE, SUPPLY AND/OR USE:

The import, sale, supply and/or use of Nobilis RT inac is/or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use Nobilis RT inac has to consult the relevant Member State's competent authorities on the current vaccination policies prior to the import, sale, supply and/or use.