Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis TRT Live

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance
Live turkey rhinotracheitis (TRT) virus, strain BUT 1#8544 $\geq 10^{2.5}$ $TCID_{50}$* per dose

* $TCID_{50}$: 50 % tissue culture infective dose

Excipients
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lyophilisate for suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens (broilers) and turkeys.

4.2 Indications for use, specifying the target species

For the active immunisation of broilers and turkeys from one day of age to reduce clinical signs of rhinotracheitis virus infection.

Onset of immunity: 3 weeks after vaccination.
Duration of immunity: 6 – 9 weeks after vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Only vaccinate healthy birds. Sick or weak birds will not develop adequate immunity following vaccination.

A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system.

Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress. Under certain conditions, for example extreme disease pressure, fully immune birds may succumb to disease. Therefore, successful vaccination may not be synonymous with full protection in the face of a disease challenge.
Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration.
Do not use chlorinated water.

4.5 Special precautions for use

Special precautions for use in animals
The vaccine virus spreads and shows some reversion to virulence on bird to bird passage. For these reasons its use is not recommended on multi-age sites.
The vaccine should not be used on sites where TRT has not been diagnosed unless challenge is anticipated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
When spraying the vaccine, to avoid hay-fever like reactions in some individuals, personal protective equipment consisting of well-fitting masks with eye protection should be worn when handling the veterinary medicinal product.

Wash and disinfect hands after vaccinating.

4.6 Adverse reactions (frequency and seriousness)

Snicking may be observed after spray vaccination.

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

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 therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

The vaccine may be administered by spray or oculo/nasal dropper administration in broiler chicks or turkey poults from one day of age.

Vaccination programme
The optimum time and method of administration depend on the local situation, and the advice of a veterinarian should be sought.

Correct administration is important to ensure optimal initial vaccine 'take'.

Spray administration
The vaccine should be dissolved in cool, clean water which is free of iron and chlorine. The appropriate number of vials should be opened under the surface of the water. The volume of water for reconstitution should be sufficient to ensure an even distribution when sprayed onto the birds. This will vary according to the age of the birds being vaccinated and the management system. The vaccine medicated water should be spread evenly over the correct number of birds, at a distance of 30 – 40 cm (12 – 16"), preferably when the birds are sitting together in dim light.
The spray apparatus should be free from sediments, corrosion and traces of disinfectants (and ideally should be used for vaccination purposes only).
The sprayer nozzles should be set to deliver a coarse spray.

Oculo/nasal dropper administration
Dissolve the vaccine in water (usually 40 ml per 1,000 doses) and administer by means of a dropper.
One drop should be applied from a height of a few centimetres (1 – 2") into one nostril or one eye. The operator should ensure that the nasal drop is inhaled by the bird.

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

At > 100 times overdose, day old poults vaccinated by the spray method showed mild symptoms of nasal discharge.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Aves; live viral vaccines; avian rhinotracheitis virus.
ATCvet code: QI01AD01

To stimulate active immunity against turkey rhinotracheitis virus.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pancreatic digest of casein
Dextran 70
Sorbitol
Sucrose
Gelatin
Dibasic potassium phosphate
Monobasic potassium phosphate
Water for injection

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 1 year.
Shelf-life after reconstitution according to directions: 2 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Carton with 1 or 10 glass type II (Ph. Eur.) vials containing 1,000, 2,500 or 5,000 doses, closed with a halogenobutyl rubber bung and sealed with a coded aluminium cap.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/088/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th December 2002

Date of last renewal: 16th December 2007

10 DATE OF REVISION OF THE TEXT

February 2016