Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis RT+IBmulti+ND+EDS

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 0.5 ml:

Active substances:
Inactivated viral antigens of:

IBV strain M41	inducing	≥ 5.5 log2 VN units*
IBV strain 249g	inducing	≥ 4.0 $\log_2$ VN units*
ART strain But1#8544	inducing	≥ 9.5 $\log_2$ ELISA units*
EDS'76 strain BC14	inducing	≥ 6.5 $\log_2$ HI units*
NDV strain Clone 30	inducing	≥ 4.0 $\log_2$ HI units per 1/50th of a dose*
	or containing	≥ 50 PD_{50} units

* serological response in chickens

Adjuvant:
Liquid Paraffin: 215 mg.

Excipients:

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Emulsion for injection (water-in-oil).
White to nearly white oily emulsion.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens (breeders and layers).

4.2 Indications for use, specifying the target species

Active immunisation of breeder and layer chickens for:

- Reduction of infection and prevention of egg drop caused by the Massachusetts serotype of Infectious Bronchitis Virus;
- Reduction of egg drop and egg shell defects caused by the D274/D207 serotype of Infectious Bronchitis Virus;
- Reduction of infection caused by Newcastle Disease Virus;
- Prevention of respiratory signs and reduction of egg drop and egg shell defects related to Avian Rhinotracheitis virus (avian pneumovirus);
- Reduction of egg drop and egg shell defects related to EDS'76 virus.

Onset of immunity: 4 weeks after vaccination
Duration of immunity: one laying period.

4.3 Contraindications

None

4.4 Special warnings for each target species

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, 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.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

Not to be used during 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 use of this vaccine when used with any other. A decision to use this vaccine before or after any other veterinary medicinal product needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

Nobilis RT+IBmulti+ND+EDS should be given to birds around 14−20 weeks of age but not later than 4 weeks before the expected onset of lay.
In the event that live vaccines were used to prime birds against Infectious Bronchitis, Rhinotracheitis and Newcastle disease, Nobilis RT+IBmulti+ND+ EDS should be given at least 4 weeks after the administration of the live vaccines.
Each bird should be given 0.5 ml of vaccine intramuscularly in the thigh or chest muscle.
Before using the vaccine allow it to reach ambient temperature (15-25°C).
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.

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

After administration of a double dose the reactions are not different from those observed after a single dose.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral vaccines.
ATCvet code: QI01AA18
The antigens are inactivated with formalin or β-propiolactone and suspended in the aqueous phase of an water in oil adjuvant emulsion, in order to enhance a prolonged stimulation of immunity.
The vaccine is intended to stimulate active immunity against Avian Rhinotracheitis virus, against the Massachusetts and D274/D207 serotypes of Infectious Bronchitis virus and against Newcastle disease and Egg Drop Syndrome '76 virus.
An enhanced immune response is obtained when the product is used for booster immunisation after priming the birds with live vaccines, if available, against Infectious Bronchitis, Rhinotracheitis and Newcastle Disease virus. Priming with Egg Drop Syndrome live vaccine is not necessary. The best results will be obtained if vaccination with the inactivated vaccine takes place at least 4 weeks after administration of the live primer.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polysorbate 80
Sorbitan mono-oleate
Glycine
Water for injections

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: 2 years.
Once broached, use within 3 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Vial of polyethylene terephthalate (PET), closed with a nitryl rubber stopper and sealed with a colour coded aluminium cap, containing 250 ml (500 doses) or 500 ml (1000 doses) of vaccine.
Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/181/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28th August 2009

10 DATE OF REVISION OF THE TEXT