Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis IBmulti+ND+EDS

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 0.5 ml:

Active substance(s)

inactivated whole virus of		
IBV strain M41:	inducing	≥ 5.5 $\log_2$ VN units*
IBV strain 249G:	inducing	≥ 4.0 $\log_2$ VN units*
EDSV 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
VN = virus neutralising
HI = haemagglutination inhibiting
PD_{50} = protective dose in 50% of the test animals
Adjuvant: Light liquid paraffin (215 mg/dose).

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Emulsion for injection (water-in-oil).

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;
-protection against egg drop caused by EDS 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 healthy birds only

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 leaflet 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 slight transient swelling may be felt at the site of vaccination.

4.7 Use during pregnancy, lactation or lay

Not to be used for 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 interactions

No information is available on the compatability of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either on the same day or shortly before/after that) has not been demonstrated.

4.9 Amounts to be administered and administration route

Nobilis 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 and Newcastle Disease, Nobilis 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, or subcutaneously into the lower part of the neck.
Before using the vaccine allow it to reach ambient temperature (15-25°C).
Shake the bottle vigorously before use and periodically during use.
Make sure 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.
Use the entire contents within 3 hours after opening.

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

No particular symptoms are observed after administration of a double dose. A slight swelling may be felt at the site of vaccination.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC vet code: QI01AA13
Pharmacotherapeutic group: Inactivated viral vaccine

Nobilis IBmulti+ND+EDS is an inactivated vaccine that contains two strains of Infectious Bronchitis virus (the Massachusetts serotype [M41] and a variant strain [249G] belonging to the D207/D274 serotype), a strain of Newcastle Disease virus and a strain of Egg Drop Syndrome
virus. The antigens are inactivated with formalin and suspended in the aqueous phase of a water-in-oil adjuvant emulsion. The vaccine is intended to stimulate active immunity against the Massachusetts and D207/D274 serotypes of Infectious Bronchitis virus, 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 virus and Newcastle Disease virus. Priming with Egg Drop Syndrome 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. The vaccine contains an oil adjuvant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light liquid parafin, polysorbate 80, sorbitan oleate, glycine, water for injection.

6.2 Major incompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf-life

2 years in glass bottles and 2 years in PET bottles.Once broached, use within 3 hours.

6.4 Special precautions for storage

Store at between +2°C and +8°C. Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Bottle of glass, hydrolytical class type II (Ph.Eur.) or of polyethylene terephthalate (PET). The bottles are closed with a nitryl rubber stopper and sealed with a 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 derived from the use of such products

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
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Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/192/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 November 2005
Date of last renewal: 23 November 2008

10 DATE OF REVISION OF THE TEXT

August 2007