SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis RT+IBmulti+ND+EDS emulsion for injection for chickens
FR: Nobilis RT Ponte emulsion for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 0.5 ml:

Active substances:
Inactivated viral antigens of:

IBV strain M41	inducing	≥ 5.5 $\log_2$ 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 $1/50^{th}$ of a dose*
	or containing	≥ 50 PD_{50} units

* serological response in chickens

Adjuvant:
Liquid paraffin: 215 mg.

Excipients:

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

White to nearly white oily emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (breeders and layers).

3.2 Indications for use for each 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 (IBV);
- Reduction of egg drop and eggshell 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 eggshell defects related to avian rhinotracheitis (ART) virus (avian pneumovirus);
- Reduction of egg drop and eggshell defects related to egg drop syndrome (EDS) '76 virus.

Onset of immunity: 4 weeks after 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:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1]

[1] A transient diffuse swelling which persists for about 14 days.

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 section “Contact details” of the package leaflet.

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

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.

3.9 Administration routes and dosage

The vaccine should be given to chickens around 14-20 weeks of age but not later than 4 weeks before the expected onset of lay.

If live vaccines were used to prime chickens against Infectious Bronchitis, Rhinotracheitis and Newcastle disease, the vaccine should be given at least 4 weeks after the administration of the live vaccines.

Each chicken 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 °C – 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.

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

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

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: QI01AA18.

The antigens are inactivated with formalin or β-propiolactone and suspended in the aqueous phase of a 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.

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: 3 hours.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
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, containing 250 ml (500 doses) or 500 ml (1000 doses) of vaccine.

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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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

{MM/YYYY}

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).
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