SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Nobilis Reo + IB + G + ND

2. QUALITATIVE AND QUANTITATIVE COMPOSITION OF PRODUCT

Active ingredient	**per dose**
Reo virus strains 1733 & 2408	inducing > 7.4 log_2 ELISA units
Infectious Bursitis virus strain M41	inducing > 6.0 log_2 HI units
Infectious Bursal (Gumboro) virus strain D78	inducing >14.5 log_2 VN units
Newcastle Disease Virus strain Clone 30	inducing > 4.0 log_2 HI units per $1/50^{th}$ dose or containing > 50 PD_{50} units
Adjuvant	
Liquid paraffin	215 mg

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (breeding birds).

4.2 Indications for use, specifying the target species

Active immunisation of breeder chickens for

- prevention of egg drop caused by the Massachusetts serotype of Infectious Bronchitis virus;
- prevention of mortality and clinical signs caused by Newcastle Disease virus;
- passive immunisation of the progeny of the vaccinated birds against Infectious Bursal Disease for at least the first four weeks;
- passive immunisation of the progeny of the vaccinated birds against Reo virus for production during the susceptible period in the early phase of life up to 7 days of age.

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

4.3 Contra-indications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the 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 further medical advice.

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 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 (resolved within 3 weeks) may be felt in 50 % of the vaccinated birds at the site of vaccination.

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay.
Not to be used within 4 weeks before the onset of lay.

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 Intervet's inactivated oil emulsion vaccines, containing the TRT or EDS antigen, administered at the same time but at separate 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 made on a case by case basis.

4.9 Amounts to be administered and administration route

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.

The product should be given to birds around 16 - 20 weeks of age but not less than 4

weeks before the expected onset of lay.
Priming with live vaccines for Infectious Bronchitis, Newcastle Disease and Gumboro disease is necessary unless serological tests indicate otherwise. The interval between priming and boosting should be more than 4 weeks and less than 6 weeks. For an optimal response to the Reovirus component in birds not primed by field virus two vaccinations should be given approximately 6 weeks apart.

Allow the vaccine to reach ambient temperature (15 °C - 25 °C) before use. Shake vigorously before and periodically during use.
An automatic injection system, incorporating a means to prevent back flushing and hence possible contamination of the vaccine should be used to administer the vaccine. Ensure that vaccination equipment is clean and sterile before use. Do not use vaccination equipment with rubber parts as the excipient may attack certain types of rubber.

4.10 Overdose (symptoms, emergency procedures, antidotes)

No other reactions than those after a single dose administration are expected.

4.11 Withdrawal periods

Zero days.

5. IMMUNOLOGICAL PROPERTIES

ATC-vet code: QI01AA16
Pharmacotherapeutic group: Immunologicals for aves, Domestic fowl, inactivated viral vaccine.

The vaccine is intended to stimulate active immunity against the Massachusetts serotypes of Infectious Bronchitis virus, against Newcastle disease, and to stimulate active immunity against Reo virus and Infectious Bursal (Gumboro) disease in order to provide passive immunity to the progeny.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light liquid paraffin, Polysorbate, Sorbitan oleate, Glycine, formaldehyde, 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: 18 months
Shelf life after first opening of the immediate packaging: 3 hours

6.4 Special precautions for storage

Store and transport at 2 °C - 8 °C. Do not freeze. Protect from light.

6.5 Nature and composition of the immediate packaging

Carton with 1 glass bottles (type II Ph.Eur) or 1 PET bottle containing 500 ml/1000 doses. The bottles are closed with a nitryl rubber stopper, sealed with a coded aluminium cap.

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

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

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor
Walton,
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

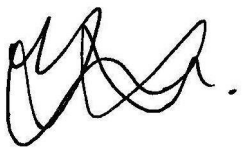
Vm 01708/4332

9. DATE OF FIRST AUTHORISATION

13 September 2005

10. DATE OF REVISION OF THE TEXT

July 2020



Approved: 03 July 2020