SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis REO inac emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of 0.5 ml contains:

Active substance:
Inactivated reovirus strains 1733 and 2408 inducing ≥ 7.4 $\log_2$ ELISA units;

Excipients: Liquid paraffin.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
White to nearly white oily emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (breeding birds).

4.2 Indications for use, specifying the target species

For the active immunisation of parent birds for the passive immunisation of their progeny, to reduce mortality and clinical signs of disease caused by avian reoviruses.
Active immunity develops in the parent within 4 weeks, and offspring born at any stage of the subsequent laying period will have passive immunity against reovirus infections for protection during the susceptible period in the early phase of life.

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 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 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)

It is very common that a slight transient swelling (resolved within 3 weeks) may be felt in 50% of the vaccinated birds at the site of vaccination.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Laying birds:
Do not use in birds in lay and within 4 weeks before the onset of the laying period.

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 other Intervet inactivated oil emulsion vaccines, containing the avian infectious bronchitis (IB), Gumboro disease (GD), Newcastle disease (ND), turkey rhinotracheitis (TRT) and/or egg drop syndrome (EDS) antigens.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product apart from the products listed 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

Intramuscular or subcutaneous use.
The vaccine Nobilis REO inac should be given to birds around 10–20 weeks of age but not later than 4 weeks before the expected onset of lay.
Dose: 0.5 ml vaccine per bird via intramuscular injection in the thigh or chest muscle or by subcutaneous injection into the back of the neck, using a medium sized needle (20g x ½"). For an optimal response 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.
The vaccine may occasionally separate into two layers on storage. This in no way affects its potency, but the vaccine should be shaken vigorously before and during use to ensure a good emulsification.
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 damage certain types of rubber.

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

Not different from single dose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Aves, inactivated viral vaccines for domestic fowl.
ATCvet code: QI01AA04.

Nobilis REO inac is an inactivated viral vaccine which contains two strains of avian reovirus.
The antigens are inactivated with formalin and suspended in the aqueous phase of a water in oil adjuvant emulsion, in order to give a prolonged stimulation of immunity.
The vaccine is intended to stimulate active immunity against avian reoviruses in the parents and passive immunity in the progeny of the vaccinated chickens.

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:
in glass bottles 1 year,
in PET bottles 2 years.

Shelf life after first opening the immediate packaging: 3 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Box with one glass bottle (type II Ph. Eur.) or one polyethylene terephthalate (PET) bottle closed with nitrile rubber stopper, sealed with a colour coded aluminium cap, containing 500 ml (1,000 doses) vaccine.

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

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

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

8. MARKETING AUTHORISATION NUMBER

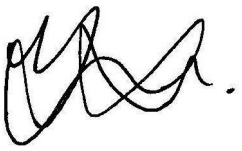
Vm 01708/4329

9. DATE OF FIRST AUTHORISATION

24 June 1995

10. DATE OF REVISION OF THE TEXT

July 2020



Approved: 03 July 2020