

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis REO Inac emulsion for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.5 ml) contains:

Active substance:

Avian reovirus strains 1733 and 2408, inactivated inducing $\geq 7.4 \log_2$ ELISA units

Adjuvant:

Liquid paraffin

Excipients:

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

Homogenous and white to nearly white emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (for reproduction).

3.2 Indications for use for each 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.

Onset of immunity: 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.

Duration of immunity: Offspring born to a vaccinated parent 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.

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 (for reproduction):

Very common (>1 animal / 10 animals treated):	Injection site swelling ¹ .
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¹ A slight transient swelling may be observed which resolves within 3 weeks and may be palpable at the site of vaccination in 50% of vaccinated birds.

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:

The safety of the veterinary medicinal product has not been established during lay. 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

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 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.

3.9 Administration routes and dosage

Intramuscular or subcutaneous use.

The veterinary medicinal product 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 by intramuscular injection into the thigh or chest muscle or by subcutaneous injection into the back of the neck, using a medium sized needle (20 g 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.

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

No symptoms were observed from a double dose other than those described in section 3.6.

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: QI01AA04.

The veterinary medicinal product 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.

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:
in glass bottles 1 year,
in PET bottles 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

Carton box with one glass bottle (type II) or one polyethylene terephthalate (PET) bottle closed with nitrile rubber stopper, sealed with a colour coded aluminium cap, containing 500 ml (1000 doses) vaccine.

Pack size:

Carton box containing 1 x bottle of 500 ml (1000 doses).

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

Medicines should not be disposed of via wastewater.

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

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4133

8. DATE OF FIRST AUTHORISATION

24 June 1995

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

October 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 08 March 2026