1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis E.coli inac emulsion for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.5 ml) of vaccine contains:

Active substances:
F11-antigen (*E.coli* fimbrial antigen) 100 µg
FT-antigen (*E.coli* flagellar toxin antigen) 100 µg

Adjuvant:
Liquid paraffin 214.42 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Formalin	0.675 mg
Polysorbate 80	
Sorbitan mono-oleate	
Sodium chloride	
Water for injections	

A homogeneous, white to nearly white emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (broiler-breeders)

3.2 Indications for use for each target species

Partial passive immunisation of broiler chickens by vaccination of the broiler breeders as a help against postnatal colibacillosis (airsac disease and septicaemia) caused by fimbrial F11-antigen and flagellar FT-antigen containing *Escherichia coli (E.coli)*.

Onset of immunity: 1 day of age (offspring)
Duration of immunity: 7 weeks (offspring)

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 granuloma[1]
Common (1 to 10 animals / 100 animals treated):	Injection site necrosis[1], injection site abscess[1]

[1] Five weeks after vaccination these local reactions are considerably decreased.

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:
Do not use in birds in lay.

3.8 Interaction with other medicinal products and other forms of interaction

Data are available which demonstrate that this vaccine can be administered on the same day but not mixed with other inactivated vaccines of the same company against avian infectious bronchitis, avian

infectious bursitis, avian tenosynovitis and Newcastle disease. The vaccines should be given at different 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.

3.9 Administration routes and dosage

Intramuscular or subcutaneous use.

Vaccination scheme:
Two injections of 0.5 ml, with an interval of at least 6 weeks. First vaccination at 6-12 weeks of age, revaccination at 14-18 weeks of age.

Before use allow the vaccine to reach room temperature (15 °C - 25 °C).
Shake well before use.
Use sterile vaccination equipment.

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

As compared to the single dose reaction, effects after administration of a double dose have the same character, but they are more severe.

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

Meat and offal: 35 days.
Eggs: zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AB05

The *E.coli* antigens are incorporated in a water in oil emulsion in order to enhance and prolong the production of antibodies against *E.coli* fimbrial antigen and *E.coli* flagellar toxin antigen.

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: 10 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

Glass Type II vial or PET vial, closed with a nitryl rubber stopper and sealed with a coded aluminium cap.

Pack sizes:
Cardboard box with one glass vial or PET vial 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

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/083/001

8. DATE OF FIRST AUTHORISATION

06 June 2000

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

19 October 2023

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)