Summary of Product Characteristics

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 substance:

F11-antigen (E.coli fimbrial antigen)	100	µg
FT-antigen (E.coli flagellar toxin antigen)	100	µg

Adjuvant:

Liquid paraffin:	214.42	mg

Excipient:

Formalin (preservative):	0.675	mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Emulsion for injection.
A homogeneous, white to nearly white emulsion.

4 CLINICAL PARTICULARS

4.1 Target Species

Chickens (broiler-breeders).

4.2 Indications for use, specifying the target species

Partial passive immunisation of broiler chickens during their first 7 weeks of life by vaccination of the broiler breeders as a help against postnatal colibacillosis (airsac disease and septicaemia) caused by fimbrial F11-antigen and flagellar Ft-toxin containing *E. coli*.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy chickens only.

4.5 Special precautions for use

Special precautions for use in animals

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 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)

In laboratory studies and field trials:
Local tissue reactions of a granulomatous nature are very commonly observed and necrosis or abscesses may commonly occur. Five weeks after vaccination these local reactions are considerably decreased.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay.

4.8 Interaction with other medicinal products and other forms of interactions

Date 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 product should be administered at different sites of injection.
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

Intramuscular or subcutaneous use in broiler breeder hens.

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.

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

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

4.11 Withdrawal period(s)

Meat and offal: 35 days
Eggs: Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Active immunisation of broiler breeders in order to provide passive immunity to broiler chickens against postnatal colibacillosis.
Pharmacotherapeutic group: Immunological for Aves, inactivated bacterial vaccines for domestic fowls, Escherichia
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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
Polysorbate
Sorbitan mono-oleate
Sodium chloride
Formalin
Water for injections

6.2 Major 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: 2 years
Shelf-life after first opening the immediate packaging: 10 hours.

6.4 Special precautions for storage

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

6.5 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).
Cardboard box with one glass vial or PET vial of 500 ml (1000 doses).
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Intervet Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/083/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 June 2000
Date of last renewal: 16 June 2010

10 DATE OF REVISION OF THE TEXT

March 2019