

## Summary of Product Characteristics

### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis E.coli inac.

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

*Per dose of 0.5 ml*

#### Active substance

F11-antigen suspension

containing 100 µg F11 (E.coli fimbrial antigen) 68.3 mg

FT-antigen suspension

containing 100 µg FT (E.coli flagellar toxin antigen) 68.3 mg

#### Adjuvant

214.42 mg liquid paraffin

#### Excipients

0.675 mg formalin (preservative)

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Emulsion for injection.

### 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

None.

## 4.5 Special precautions for use

### Special precautions for use in animals

Vaccinate healthy chickens only.

### Special precautions to be taken by the person administering the veterinary medicinal 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 medical advice again.

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 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)

Local tissue reactions of a granulomatous nature and in a number of cases necrosis or abscesses occur. Five weeks after vaccination the local reactions are considerably decreased.

## 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 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 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 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 injection 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.

ATCvet classification: Domestic fowl, inactivated bacterial vaccine, 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 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

Cardboard box with 1 glass (hydrolytic Type II) or PET vial of 250 or 500 ml with a nitril rubber stopper and sealed with a coded aluminium cap.

Not all pack sizes may be marketed.

#### 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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 Ltd.  
Magna Drive  
Magna Business Park  
Citywest Road  
Dublin 24

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10996/083/001

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

16<sup>th</sup> June 2010

## **10 DATE OF REVISION OF THE TEXT**