

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 animals 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 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 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 (15-25 °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. IMMUNOLOGICAL PROPERTIES

Active immunization 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 nitril 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 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 01708/4266

9. DATE OF FIRST AUTHORISATION

30 December 1994

10. DATE OF REVISION OF THE TEXT

August 2020

Approved 14 August 2020

A handwritten signature in black ink, appearing to read "Hunter.", is positioned below the approval date. The signature is stylized and includes a period at the end.