

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis E.coli inac emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

One dose of 0.5 ml contains:

F11-antigen (<i>E.coli</i> fimbrial antigen)	100 µg
FT-antigen (<i>E.coli</i> flagellar toxin antigen)	100 µg

3. PACKAGE SIZE

250 ml (500 doses)
500 ml (1000 doses)

4. TARGET SPECIES

Chickens (broiler-breeders)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous or intramuscular use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.

Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/5011

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Accidental administration is dangerous

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription.

PARTICULARS TO APPEAR ON THE IMMEDIATE LABEL

Vial label (Glass or PET vial of 250 ml or 500 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis E.coli inac emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

250 ml (500 doses)
500 ml (1000 doses)

One dose of 0.5 ml contains:

F11-antigen (<i>E.coli</i> fimbrial antigen)	100 µg
FT-antigen (<i>E.coli</i> flagellar toxin antigen)	100 µg

3. TARGET SPECIES

Chickens (broiler-breeders)

4. ROUTES OF ADMINISTRATION

SC or IM

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.

Protect from light.

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

9. BATCH NUMBER

Lot {number}

10. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.

11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis E.coli inac Emulsion for injection for chickens

2. 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 : 0.675 mg

A homogeneous, white to nearly white emulsion.

3. TARGET SPECIES

Chickens (broiler-breeder).

4. INDICATIONS FOR USE

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-antigencontaining *Escherichia coli* (*E. coli*).

Onset of immunity: 1 day of age (offspring)

Duration of immunity: 7 weeks (offspring)

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNINGS

Special warnings:

Vaccinate healthy animals only.

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.

Laying birds:

Do not use in birds in lay.

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.

Overdose:

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

Special restrictions for use and special conditions for use:

Not applicable.

Major Incompatibilities:

Do not mix with any other veterinary medicinal product.

7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

Before use allow the vaccine to reach room temperature (15 °C – 25 °C).

Shake well before use.

Use sterile vaccination equipment.

10. WITHDRAWAL PERIODS

Meat and offal: 35 days.

Eggs: zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).

Do not freeze.

Protect from light.

Do not use this medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf-life after first opening the container: 10 hours.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

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 applicable national collection systems. These measures should help to protect the environment. Ask your veterinary surgeon how to dispose of medicines no longer required.

Ask your veterinary surgeon how to dispose of medicines no longer required.

UK(GB) only: Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 06376/5011

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. CONTACT DETAILS

Marketing authorisation holder:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Manufacturer responsible for batch release:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Contact details to report suspected adverse reactions:

MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

17. OTHER INFORMATION

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.

POM-V Veterinary medicinal product subject to prescription.

Gavin Hall

Approved 10 December 2024