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 for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

One dose of 0.5 ml contains:

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

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Chickens (broiler-breeders)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous or intramuscular use.

Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

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

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4266

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

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 for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

One dose of 0.5 ml contains:

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

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Chickens (broiler-breeders)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

SC or IM

Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4266

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Nobilis E.coli inac
Emulsion for injection for chickens

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis E.coli inac

Emulsion for injection for chickens

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

A homogeneous, white to nearly white emulsion.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Chickens (broiler-breeders).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

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

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

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.

Lay:
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 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.

Overdose (symptoms, emergency procedures, antidotes):
As compared to the single dose reaction, effects after administration of a double dose have the same character, but they are more severe.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. 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.

Pack sizes:
Cardboard box with one glass or PET vial of 250 ml (500 doses).
Cardboard box with one glass or PET vial of 500 ml (1000 doses).

Not all pack sizes may be marketed.

Vm 01708/4266

Approved 14 August 2020