ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis OR inac emulsion for injection for chickens

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 0.25 ml:
Inactivated whole cell suspension of *Ornithobacterium rhinotracheale* serotype A strain B3263/91 1 x 10^7 cells *

* inducing a mean titre in the chickens of the potency test of at least 11.2 (log_2).

Light liquid paraffin: 107.21 mg
Traces of formaldehyde

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

1 PET vial with 250 ml (1000 doses)
1 PET vial with 500 ml (2000 doses)

5. TARGET SPECIES

Chickens

6. INDICATION(S)

For passive immunisation of broilers induced by active immunisation of female broiler breeders to reduce infection with *Ornithobacterium rhinotracheale* serotype A when this agent is involved. Under field conditions passive immunity is transferred during lay for 43 weeks after the last vaccination of broiler breeders, resulting in a duration of passive immunity in broilers of at least 14 days after hatching.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous injection in the neck or intramuscular injection in the breast of one dose of 0.25 ml.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Oil adjuvanted vaccine
Do not use for birds in lay.
Accidental injection is dangerous – see package insert before use.

10. EXPIRY DATE

EXP: (Month/Year) ……/…..
Shelf life after first opening: Use immediately after opening

11. SPECIAL STORAGE CONDITIONS

Store and transport at 2 - 8°C. Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with the local requirements.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/5045

17. MANUFACTURER'S BATCH NUMBER

Lot: ……

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis OR inac emulsion for injection for chickens

2. ACTIVE SUBSTANCE(S)

Inactivated whole cell suspension of *O. rhinotracheale*
Light liquid paraffin

3. CONTENTS BY WEIGHT, BY VOLUME OR NUMBER OF DOSES

250 ml (1000 doses)
500 ml (2000 doses)

4. TARGET SPECIES

Chickens

5. ROUTES OF ADMINISTRATION

s.c. injection or i.m. injection of one dose of 0.25 ml.

6. WITHDRAWAL PERIOD

Withdrawal period: 0 days

7. SPECIAL WARNINGS

Do not use for birds in lay.
Accidental self-injection is dangerous – see package insert

8. EXPIRY DATE

(Month/Year) ……/…..
Once broached: Use immediately

9. SPECIAL STORAGE CONDITIONS

Store and transport at 2 - 8°C. Do not freeze.

10. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

11. NAME OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE IN THE EEA, IF DIFFERENT

Intervet International

12. MANUFACTURER'S BATCH NUMBER

Batch: ……

13. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/5045

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Nobilis OR 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 IN THE EEA

Marketing authorisation holder and manufacturer:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis OR inac emulsion for injection for chickens

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

Per dose of 0.25 ml:

Inactivated whole cell suspension of *Ornithobacterium rhinotracheale* serotype A strain B3263/91 1 x 10^7 cells *

* inducing a mean titre in the chickens of the potency test of at least 11.2 (log_2).

Light liquid paraffin: 107.21 mg
Traces of formaldehyde

4. INDICATION(S)

For passive immunisation of broilers induced by active immunisation of female broiler breeders to reduce infection with *Ornithobacterium rhinotracheale* serotype A when this agent is involved. Under field conditions passive immunity is transferred during lay for 43 weeks after the last vaccination of broiler breeders, resulting in a duration of passive immunity in broilers of at least 14 days after hatching.

5. CONTRAINDICATIONS

Do not use for birds in lay

6. ADVERSE REACTIONS

In laboratory studies, a local transient swelling was found at post mortem examination in up to 40% of the birds for at least 14 days after subcutaneous vaccination. Under field conditions, sporadic local and systemic clinical reactions have been reported.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens

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

Single dose of 0.25 ml.

Subcutaneous injection in the neck or intramuscular injection in the breast of the chicken.

9. ADVICE ON CORRECT ADMINISTRATION

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

Vaccination scheme:
The vaccination scheme consists of two injections with a dose of 0.25 ml, administered subcutaneously in the neck or intramuscularly in the breast. The first injection can be administered at an age of 6 - 12 weeks. The second injection has to be administered at least 6 weeks later at an age of 14 - 18 weeks.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store and transport at 2 - 8°C.
Do not freeze.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

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 insert 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.

No other undesirable effects have been observed after administration of a double dose when compared with a single dose of vaccine.
Occasionally hardened minor local swellings (0.5 – 2.0 cm) were observed which disappeared within 21 days after vaccination.

Do not mix with any other vaccine/immunological product.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with the local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

10 January 2008

15. OTHER INFORMATION

For animal treatment only.

The product contains the inactivated whole cells of *Ornithobacterium rhinotracheale* serotype A, strain B3263/91 mixed with an oil adjuvant. The vaccine is to stimulate active immunity in broiler breeders in order to provide passive immunity to the progeny against *Ornithobacterium rhinotracheale* serotype A.

Approved: 06 April 2022