# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis OR inac emulsion for injection for chickens

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 0.25 ml:

**Active substance**
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 ($log_2$).

**Adjuvant**
Light liquid paraffin: 107.21 mg

**Excipients**
Traces of formaldehyde

For a list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Emulsion for injection

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Chickens

### 4.2 Indications for use, specifying the target species

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.

## 4.3 Contraindications

Do not use in birds in lay.

## 4.4 Special warnings

None

## 4.5 Special precautions for use

### Special precautions for use in animals

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

### 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 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.

## 4.6 Adverse reactions (frequency and seriousness)

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.

## 4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay (see section 4.3).

## 4.8 Interactions with other medicinal products and other forms of interaction

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.

### 4.9 Amounts to be administered and administration route

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.

### 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

### 4.11 Withdrawal period

Zero days.

## 5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated bacterial vaccine
ATCvet code: QI 01AB07

The vaccine is to stimulate active immunity in broiler breeders in order to provide passive immunity to the progeny against *Ornithobacterium rhinotracheale* serotype A

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Light liquid paraffin, Polysorbate 80, Sorbitan oleate, phosphate buffered aqueous solution

### 6.2 Incompatibilities

Do not mix with any other vaccine/immunological product.

### 6.3 Shelf life

15 months
Shelf life after first opening: Use immediately after opening.

### 6.4 Special precautions for storage

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

### 6.5 Nature and composition of immediate packaging

Carton box with one Polyethylene Terephthalate (PET) vial of 250 ml (1000 doses) or 500 ml (2000 doses), closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

### 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

## 7. MARKETING AUTHORISATION HOLDER

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

## 8. MARKETING AUTHORISATION NUMBER

Vm 01708/5045

## 9. DATE OF FIRST AUTHORISATION

24 January 2003

## 10. DATE OF REVISION OF THE TEXT

April 2022

## PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of the product is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use the product must consult the relevant Member States Competent Authority on the current vaccination policies prior to the import, sale, supply and/or use.

Approved: 06 April 2022