PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis MG 6/85 lyophilisate for oculonasal suspension for chicken

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of reconstituted vaccine:
Live attenuated *Mycoplasma gallisepticum* strain MG 6/85: $10^{6.9}$ - $10^{8.5}$ CFU[1]

[1]Colony Forming Units

3. PACKAGE SIZE

1 x 500 doses
1 x 1 000 doses
1 x 2 000 doses
10 x 500 doses
10 x 1 000 doses
10 x 2 000 doses

4. TARGET SPECIES

Chickens (pullets for egg production, future layers).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Nebulisation use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 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.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/5043

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL (Glass, 20 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis MG 6/85

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

500 doses
1 000 doses
2 000 doses

Live *Mycoplasma gallisepticum* strain MG 6/85: $10^{6.9}$ - $10^{8.5}$ CFU per dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

5. ROUTE(S) OF ADMINISTRATION

Nebulisation use.

6. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis MG 6/85 lyophilisate for oculonasal suspension for chickens

2. COMPOSITION

Per dose of reconstituted vaccine:

Active substance:
Live attenuated *Mycoplasma gallisepticum* strain MG 6/85: $10^{6.9}$ - $10^{8.5}$ CFU[1]

[1]Colony Forming Units

Lyophilisate: off-white to yellowish coloured pellet.

3. TARGET SPECIES

Chickens (pullets for egg production, future layers).

4. INDICATIONS FOR USE

Active immunisation of future layers to reduce airsacculitis and tracheitis lesions caused by *Mycoplasma gallisepticum*.

Onset of immunity: 4 weeks.
Duration of immunity: 24 weeks (using a typical batch containing 7.5 $\log_{10}$ CFU).

5. CONTRAINDICATIONS

Do not use in future breeders.

6. SPECIAL WARNINGS

Special warnings:
Vaccinate healthy animals only.
Do not use antibiotics or other substances with any microbial activity known to inhibit *M. gallisepticum*.

Special precautions for safe use in the target species:
It is not recommended to vaccinate in the presence of (sub-)clinical infection with *M. gallisepticum.*

Vaccinated future layers may excrete the vaccine strain up to 15 weeks following vaccination. The vaccine strain can spread to other birds than chicken and turkeys, such as game birds, geese and ducks. Special precautions should be taken to avoid spreading of the vaccine strain to those species.
Seroconversion may occur after vaccination.
The vaccine strain can be differentiated from wild *Mycoplasma gallisepticum* based on routine DNA analysis.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
To avoid skin and eye injuries as well as inhalation or ingestion, personal protective equipment consisting of a mask, gloves and eye protection should be worn when handling the veterinary medicinal product.
Wash and disinfect hands after vaccinating.

Laying birds:
Do not use in birds in lay and within 4 weeks before the start of the laying period.

Interaction with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. 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:
Ten times a maximum dose is safe for the target species.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. ADVERSE EVENTS

None known.

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 marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

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

After reconstitution, administer 1 dose of vaccine by nebulisation (fine-spray) to chickens (future layers) from 6 weeks of age.

9. ADVICE ON CORRECT ADMINISTRATION

Use the entire contents when first opened.

Preparation of vaccine

1. Use only clean, cool, non-chlorinated, preferably distilled water of ≤ 25 °C. The volume of water for reconstitution should be sufficient to ensure an even distribution when sprayed onto the birds. This will vary according to the size of the birds being vaccinated and the management system, but 250 to 400 ml of water per 1 000 doses is recommended. Follow the instructions of the fine-spraying device.

2. Open the vial submerged under water.
3. Remove the seal and stopper from the vial.

The reconstituted vaccine must be clear, with no flocculation and sediments.

Administration
1. Vaccinate with a fine-spraying device suitable for nebulisation application of vaccines (particle size: < 100 µm). The vaccine suspension should be spread evenly over the correct number of birds, at a distance of approximately 40 cm.
2. Do not use any disinfectants, skimmed milk or other agents impairing the performance of the vaccine in the fine-spraying device.
3. Shut off all fans and close air-inlets while fine-spray vaccinating.
4. Clean the fine-spraying device thoroughly after use according to the manufacturer's recommendation.

10. WITHDRAWAL PERIODS

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 veterinary medicinal product after the expiry date stated on the bottle. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: 2 hours.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 06376/5043

Pack sizes:
Cardboard box with 1 or 10 vial(s) of 500 doses,1 000 doses or 2 000 doses of lyophilisate.

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 and contact details to report suspected adverse reactions:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

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

17. OTHER INFORMATION

POM-V Veterinary medicinal product subject to prescription.

For animal treatment only.

Gavin Hall
Approved: 22 April 2025