SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis MG 6/85 lyophilisate for oculonasal suspension for chickens

2. QUALITATIVE AND QUANTITATIVE 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

Excipients:
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension.

Appearance: Off-white to yellowish coloured pellet.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (pullets for egg production, future layers).

4.2 Indications for use, specifying the target species

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).

4.3 Contraindications

Do not use in future breeders.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

Do not use antibiotics or other substances with any antimicrobial activity known to inhibit *M. gallisepticum*.

4.5 Special precautions for use

Special precautions for use in animals
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 birds other 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.

Special precautions for the protection of the environment
Not applicable.

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also section 16 of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amount(s) to be administered and administration route

After reconstitution, administer 1 dose of vaccine by nebulisation (fine-spray) to chickens (future layers) from 6 weeks of age.
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.
Reconstituted product: clear suspension, with no flocculation and sediments.

Administration

1. Vaccinate with a fine-spraying device suitable for nebulization 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.

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

Ten times a maximum dose is safe for the target species.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for *Aves*, domestic fowl; live bacterial vaccines, mycoplasma

ATCvet code: QI01AE03

To stimulate active immunity against *Mycoplasma gallisepticum*.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Sodium dihydrogen phosphate dihydrate
L-glutamic acid, monosodium salt
Sucrose
NZ Amine AS
Lactalbumin hydrolysate
Gelatine
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product except the solvent recommended for use with the veterinary medicinal product and except those mentioned in section 4.8 above

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 21 months.
Shelf life after reconstitution according to directions: 2 hours.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Glass vials (20 ml, of hydrolytical class type I) closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

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.

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

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.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 06376/5043

9. DATE OF FIRST AUTHORISATION

21 February 2002

10. DATE OF REVISION OF THE TEXT

April 2025

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 22 April 2025