

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} CFU¹

¹Colony Forming Units

Excipients:

Qualitative composition of excipients and other constituents
Sodium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Sodium dihydrogen phosphate dihydrate
L-glutamic acid, monosodium salt
Sucrose
Pancreatic digest of casein
Lactalbumin hydrolysate
Gelatine
Water for injections

Lyophilisate: off-white to yellowish coloured pellet.

3. CLINICAL INFORMATION

3.1 Target species

Chickens (pullets for egg production, future layers).

3.2 Indications for use for each target species

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

Onset of immunity: 4 weeks after vaccination.

Duration of immunity: 24 weeks after vaccination (using a typical batch containing 7.5 log₁₀ CFU).

3.3 Contraindications

Do not use in future breeders.

3.4 Special warnings

Vaccinate healthy animals only.

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

3.5 Special precautions for use

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 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.

3.6 Adverse events

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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 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.

3.9 Administration routes and dosage

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 1000 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 or 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AE03.

To stimulate active immunity against *Mycoplasma gallisepticum*.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product .

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Glass vial (20 ml, 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.

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

Medicines should not be disposed of via wastewater.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/3045

8. DATE OF FIRST AUTHORISATION

21 February 2002

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

April 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

Gavin Hall
Approved: 22 April 2025