SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NOBILIS MG 6/85, lyophilisate for suspension for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s):

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

Excipient(s):

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension
Off-white to yellowish coloured pellet

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (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*.
Immunity develops within 4 weeks after vaccination. A duration of immunity of 24 weeks after vaccination was established using a typical batch containing 7.5 $\log_{10}$ CFU.

4.3 Contraindications

Not to be used within four weeks of onset of egg production or during lay. Not intended for future breeders.

4.4 Special warnings for each target species

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

Vaccinate healthy chickens only. It is not recommended to vaccinate in the presence of (sub-) clinical infection with *M. gallisepticum.*
After vaccination the vaccine strain *Mycoplasma gallisepticum* MG 6/85 can be isolated in birds for at least 15 weeks. Care should be taken to prevent spread of the vaccine strain to other birds than chicken and turkeys, such as game birds, geese and ducks. 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 digestion, 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.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

See section 4.3

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Nobilis MS Live (in member states where this product is authorized). The product literature of Nobilis MS Live should be consulted before administration of the mixed product. The mixed product is not to be used within four weeks of onset of egg production or during lay. The adverse effects observed after administration of one dose or an overdose of Nobilis MG 6/85 and Nobilis MS Live are not different from those described for Nobilis MG 6/85 alone. When mixed with Nobilis MS Live, the demonstrated efficacy claims are comparable to those described for Nobilis MG 6/85 alone.
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 Amounts 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 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.
4. In case of mixed-use, repeat steps 2 and 3 in the same water using a vial of Nobilis MS Live containing the same number of doses.

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

To stimulate active immunity against *Mycoplasma gallisepticum*
ATC Vet code QI01AE03.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate

Sodium dihydrogen
Phosphate dihydrate
L-glutamic acid monosodium, sucrose
NZ Amine AS
Lactalbumin hydrolisate
Gelatine

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product, except Nobilis MS Live or the solvent recommended for use with the veterinary medicinal product.

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 - 8ºC).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Cardboard box containing one or ten 20 ml glass vials of hydrolytical class type I containing 500, 1000, 2000 doses of lyophilisate. The vial is closed with a halogenobutyl rubber stopper and sealed with a coded aluminium cap.

Package sizes:
Cardboard box with 1 vial of 500 doses of lyophilisate.
Cardboard box with 1 vial of 1000 doses of lyophilisate.
Cardboard box with 1 vial of 2000 doses of lyophilisate.
Cardboard box with 10 vials of 500 doses of lyophilisate.
Cardboard box with 10 vials of 1000 doses of lyophilisate.
Cardboard box with 10 vials of 2000 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, if appropriate

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

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

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4480

9. DATE OF FIRST AUTHORISATION

21 February 2002

10. DATE OF REVISION OF THE TEXT

August 2020

Approved 14 August 2020