

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NOBILIS MG 6/85, lyophilisate for suspension for chickens

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Live attenuated *Mycoplasma gallisepticum* strain MG 6/85: $10^{6.9}$ - $10^{8.5}$ CFU¹ per dose

¹Colony Forming Units

3. PHARMACEUTICAL FORM

Lyophilisate for suspension

4. PACKAGE SIZE

1 x 500 doses
1 x 1000 doses
1 x 2000 doses
10 x 500 doses
10 x 1000 doses
10 x 2000 doses

5. TARGET SPECIES

Chickens (future layers)

6. INDICATION(S)

Active immunisation against *Mycoplasma gallisepticum*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Nebulisation (aerosol vaccination) (Read package leaflet before use).

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

10. EXPIRY DATE

Exp: {month/year}

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Protect from light.
Do not freeze.
Use within 2 hours after reconstitution.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4480

17. MANUFACTURER’S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis MG 6/85

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 x 500 doses
1 x 1000 doses
1 x 2000 doses
10 x 500 doses
10 x 1000 doses
10 x 2000 doses

4. ROUTE(S) OF ADMINISTRATION

Nebulisation (aerosol vaccination)

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

Exp: {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET

Nobilis MG 6/85, lyophilisate for suspension for chickens

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NOBILIS MG 6/85, lyophilisate for suspension for chickens

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Per dose of reconstituted vaccine:

Live attenuated *Mycoplasma gallisepticum* strain MG 6/85 : $10^{6.9} - 10^{8.5}$
CFU¹

¹Colony Forming Units

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

None.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens (future layers)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 $\leq 25^{\circ}\text{C}$. 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: $< 100\ \mu\text{m}$). 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 PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store between $2 - 8^{\circ}\text{C}$. Protect from light

Do not use after the expiry date stated on the bottle

Shelf life of the veterinary medicinal product as packaged for sale: 21 months

Shelf-life after reconstitution according to directions: 2 hours

12. SPECIAL WARNING(S)

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

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.

Vaccinate healthy chickens only. It is not recommended to vaccinate in the presence of (sub-) clinical infection with *M. gallisepticum*.

Do not mix with any other immunological product than Nobilis MS Live.

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.

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 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

Cardboard box containing one or ten 20 ml glass vials containing 500, 1000, 2000 doses of lyophilisate.

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.

Approved 14 August 2020

A handwritten signature in black ink, appearing to read "J. Hunter.", is positioned below the approval date.