~~*[Version 9,03/2022] corr. 11/2022*~~

SUMMARY OF PRODUCT CHARACTERISTICS

Draft /111300 / 7.0

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

~~NOBILIS~~ 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:

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: ~~O~~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: ~~Immunity develops within~~ 4 weeks after vaccination.
~~A d~~Duration of immunity: ~~ of~~ 24 weeks after vaccination ~~was established~~(~~-~~using a typical batch containing 7.5 $\log_{10}$ CFU).

3.3 Contraindications

~~Not to be used within four weeks of onset of egg production or during lay. Not intended for~~Do not use in future breeders.

3.4 Special warnings

Vaccinate healthy animals only.
~~Vaccinate healthy chickens only. It is not recommended to vaccinate in the presence of (sub-) clinical infection with *M. gallisepticum*.~~
Do not use antibiotics or other substances with any antimicrobial activity known to inhibit *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.~~

3.5 Special precautions for use

Special precautions for safe use in the target species:

~~Do not use antibiotics or other substances with any antimicrobial activity known to inhibit *M. gallisepticum*.~~
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.~~Vaccinated future layers may excrete the vaccine strain up to 15 weeks following vaccination.
~~Care should be taken to prevent spread of the vaccine strain to other birds than~~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 ~~digestion~~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.
{< > to be adjusted nationally}

3.7 Use during pregnancy, lactation or lay

~~See section 4.3.~~Do not use in birds in lay and within 4 weeks before the start of the laying period.

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3.8 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.

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.
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.~~

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.

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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~~, except Nobilis MS Live or the solvent recommended for use with the 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~~2 – 8ºC~~).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

~~Cardboard box containing one or ten 20 ml g~~Glass vial (20 ml, hydrolytical class type I)~~s 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.

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

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 <or household waste>.
{< > to be adjusted nationally}

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

6. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name} {to be completed nationally}

7. MARKETING AUTHORISATION NUMBER(S)

{MA numbers} {to be completed nationally}

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}. {to be completed nationally}

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

{MM/YYYY} {to be completed nationally}

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).

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

~~NOBILIS~~ Nobilis MG 6/85~~,~~ lyophilisate for oculonasal suspension ~~for chickens~~

2. STATEMENT OF ACTIVE SUBSTANCES

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

[1]Colony Forming Units

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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 ~~(aerosol vaccination)~~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

{to be completed nationally}

14. MARKETING AUTHORISATION NUMBERS

{to be completed nationally}

15. BATCH NUMBER

Lot {number}

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. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

500 doses
1 000 doses
2 000 doses

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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.

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B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

~~NOBILIS~~ 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: ~~O~~ooff-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: ~~Immunity develops within~~ 4 weeks after vaccination.
~~A d~~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~~Do not use in future breeders.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.
~~Vaccinate healthy chickens only.~~ Do not use antibiotics or other substances with any antimicrobial activity known to inhibit *M. gallisepticum.*
~~It is not recommended to vaccinate in the presence of (sub-) clinical infection with *M. gallisepticum.*~~

Special precautions for safe use in the target species:
~~Do not use antibiotics or other substances with any antimicrobial activity known to inhibit *M. gallisepticum.*~~
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~~Vaccinated future layers may excrete the vaccine strain up to 15 weeks following vaccination. ~~Care should be taken to prevent spread of the vaccine strain to other birds~~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. ~~Special precautions should be taken to avoid spreading of the vaccine strain to those species.~~
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~~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.

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~~Special precautions for the protection of the environment:~~
~~Not applicable.~~

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:
~~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.

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

~~Special restrictions for use and special conditions for use:~~
~~Not applicable.~~

Major incompatibilities:
Do not mix with any other ~~immunological~~ veterinary medicinal product ~~than Nobilis MS Live the solvent recommended for use with the 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 <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

{< > to be adjusted nationally}

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 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.~~

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.

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).~~Store between 2 - 8ºC.~~
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 of the veterinary medicinal product as packaged for sale: 21 months~~
Shelf -life after reconstitution according to directions: 2 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.

{< > to be adjusted nationally}

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required. ~~Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.~~

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

{MA numbers} {to be completed nationally}

Pack~~age~~ sizes:
Cardboard box with 1 or 10 vial(s) of 500 doses, 1000 doses or 2000 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.

15. Date on which the package leaflet was last revised

{MM/YYYY} {to be completed nationally}

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

16. Contact details

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:
{< > to be adjusted nationally}

<Manufacturer responsible for batch release:> {to be adjusted nationally if included in the above}
Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>
{< > to be adjusted nationally}

<Local representative <and contact details to report suspected adverse reaction:>>
{< > to be adjusted nationally}

17. Other information

{to be completed nationally}

Any additional information concerning distribution, possession or any necessary precaution in conformity with the marketing authorisation and in accordance with article 14(2) and/or national requirements may appear in this rectangle boxed area