1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis MS Live, lyophilisate for oculonasal suspension for chickens
ES: Nobilis MS Viva
BE and LU: Nobilis Mycoplasma S

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of reconstituted vaccine:

Active substance:
Live attenuated *Mycoplasma synoviae* strain MS1: $\geq 10^{6.5}$ and $\leq 10^{8.0}$ CFU[1]

[1]Colony Forming Units

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension.
Lyophilisate: Off-white to yellowish-coloured pellet.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (layers).

4.2 Indications for use

For the active immunisation of chickens (layers) from 6 weeks of age to reduce air sac lesions, ovary lesions, and a drop in egg production due to infection caused by *Mycoplasma synoviae*.

Onset of immunity: 4 weeks.
Duration of immunity: 44 weeks.

4.3 Contraindications

None.

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 *Mycoplasma synoviae*.

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 *Mycoplasma synoviae*.

The vaccine strain has been detected in the respiratory tract of vaccinated chickens by PCR at 34 weeks after vaccination. Taking into account the potential spread of the vaccine strain by direct or indirect transmission, all chickens in the chicken house should be vaccinated. Adequate biosecurity

measures should be in place, such as change of clothing and boots and the use of properly disinfected equipment.
After vaccination interference with serological screening methods for *Mycoplasma* infections may occur, but the vaccine strain can be differentiated from wildtype *Mycoplasma synoviae* by PCR or by culture in *Mycoplasma* growth medium containing nicotinamide instead of NAD.

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

Can be used during lay.

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 MG 6/85 (in member states where this product is authorized). The product literature of Nobilis MG 6/85 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 Nobilis MS Live vaccine strain may spread from vaccinated to unvaccinated chickens in case it is used mixed with Nobilis MG 6/85. The adverse effects observed after administration of one dose or an overdose of the mixed vaccines are not different from those described for Nobilis MS Live alone. When mixed with Nobilis MG 6/85, the demonstrated efficacy claims are not different from those described for Nobilis MS Live alone.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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 oculonasal route (fine-spray) to chickens (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 MG 6/85 containing the same number of doses.

Administration

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

None.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: live bacterial vaccines for poultry
ATC vet code: QI01AE03

To stimulate active immunity in chicken against *Mycoplasma synoviae*.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium dihydrogen phosphate dihydrate
Disodium hydrogen phosphate dihydrate
Glutamine
Sodium chloride
Sucrose
Pancreatic digest of casein
Lactalbumin hydrolysate
Gelatin

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product, except Nobilis MG 6/85 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: 2 years.
Shelf life after dilution or 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 vial of hydrolytical class type I containing 500, 1000 or 2000 doses of lyophilisate. The vial is closed with a halogenobutyl rubber stopper and sealed with an 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

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

7. MARKETING AUTHORISATION HOLDER

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands
As represented by the national companies in the member states.

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

[To be completed nationally]

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.