PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis MS Live, lyophilisate for oculonasal suspension for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of reconstituted vaccine:
≥$10^{6.5}$ and ≤$10^{8.0}$ CFU[1] of live attenuated *Mycoplasma synoviae* strain MS1

[1]Colony Forming Units

3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension

4. PACKAGE SIZE

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

5. TARGET SPECIES

Chickens (layers)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oculonasal use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

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

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Vm 01708/4607

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial (20 ml) – 500/1000/2000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis MS Live lyophilisate for oculonasal suspension for chickens

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Live attenuated *Mycoplasma synoviae* strain MS1

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

500 doses
1000 doses
2000 doses

4. ROUTE(S) OF ADMINISTRATION

Oculonasal use.

5. WITHDRAWAL PERIOD(S)

[Left blank intentionally]

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 2 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET:

Nobilis MS Live, Lyophilisate for oculonasal suspension for chickens

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

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. 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

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

Per dose of reconstituted vaccine:
Live attenuated *Mycoplasma synoviae* strain MS1: $\geq 10^{6.5}$ and $\leq 10^{8.0}$ CFU[1]

[1]Colony Forming Units

Lyophilisate: Off-white to yellowish-coloured pellet.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None.

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 inform your veterinary surgeon.

7. TARGET SPECIES

Chickens (layers).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

After reconstitution, administer 1 dose of vaccine by oculonasal route (fine-spray) to chickens (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 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.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

Shelf life after dilution or reconstitution according to directions: 2 hours.

12. SPECIAL WARNING(S)

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*.

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.

Lay:
Can be used during lay.

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.

Overdose (symptoms, emergency procedures, antidotes):
None.

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.

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

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

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