SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis SE live lyophilisate for use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION Active substance:

Each dose contains:
Live, attenuated *Salmonella enterica* subsp. *enterica* serovar Enteritidis strain CAL10 Sm+/Rif+/Ssq-, 1-6 x 10^8 CFU*
For the full list of excipients, see section 6.1.

*CFU: Colony Forming Unit

3. PHARMACEUTICAL FORM

Lyophilisate for use in drinking water
White-beige to white-brown pellet

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (future layers and breeders)

4.2 Indications for use, specifying the target species

Chickens (future layers and breeders): Active immunisation to reduce colonisation of internal organs and faecal excretion of *Salmonella* Enteritidis field strains.

Onset of immunity: 14 days after the first vaccination and 4 weeks after the third vaccination

Duration of immunity: 60 weeks after completion of the recommended three vaccination schedule

4.3 Contraindications

Does not use in birds in lay.

4.4 Special warnings for each target species

Vaccinate healthy animals only.
The differentiation between vaccine and field strains is done by means of an antibiogram. In contrast to field strains, vaccine strains are sensitive to erythromycin

(recommended concentration 30 µg/ml) and resistant to streptomycin and rifampicin (recommended concentration 200 µg/ml).
Depending on the test system used, oral vaccination may result in low seropositive reactions of individual birds in a flock. Since serological Salmonella monitoring is a flock test only, positive findings have to be confirmed, e.g. by bacteriology.
The efficacy of the vaccine has not been investigated in the presence of maternally derived antibodies.

4.5 Special precautions for use

Special precautions for use in animals
Vaccinate only healthy birds. Not tested in ornamental and pure-bred poultry.
The vaccine strain may spread to susceptible birds in contact with vaccinates by shedding. Vaccinated birds may shed the vaccine strain until 21 days after the first vaccination. Susceptible birds in contact with vaccinates just after the first vaccination may shed the vaccine strain until 14 days after vaccination. Level and duration of spread of the vaccine strain markedly decreases with subsequent vaccinations.
Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible species.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product. Open bottle under water to avoid aerosols. Disinfect and wash hands after handling vaccine. Do not ingest. If the vaccine has been swallowed seek medical advice. The vaccine strain is sensitive to a number of antibiotics including quinolones (ciprofloxacin). Care should be taken to wash and disinfect hands after handling poultry faeces, particularly in the first 21 days after vaccination of birds. Immunocompromised persons are advised to avoid contact with the vaccine and vaccinated animals during handling and 28 days following vaccination.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Do not use within 3 weeks before the onset of lay and during the laying period.

4.8 Interaction with other medicinal products and other forms of interaction

The vaccine strain is highly sensitive to chemotherapeutics as quinolone antibiotics and has increased sensitivity to erythromycin, chloramphenicol and doxycycline detergents and environmental noxae. This product can be administered 3 days after or before the administration of these chemotherapeutics which are effective against Salmonella. If this is inevitable, the flock must be re-immunized.
The efficacy of this product can be compromised by the simultaneous use of Gumboro, Eimeria and Marek live vaccines given at one day of age. 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 made on a case to case basis.

4.9 Amounts to be administered and administration route

Dosage and use
The vaccine can be used as from the 1st day of life (during the first 36 hours of life).
In drinking water use

Vaccination schedule
Chickens (future layers and breeders): A single dose from one day of age, followed by a second vaccination at 7 to 8 weeks of age and a third vaccination at 16-20 weeks at least 3 weeks before the onset of the laying period.

Dosage Regimen
Make sure that all conduit pipes, tubing, troughs, drinkers etc. are thoroughly clean and free of any traces of disinfectants, detergents, soap etc.
Use only fresh drinking water, free of chlorine and metal ions at ≤ 25 °C. Do not reconstitute the vaccine with chlorinated water. A dechlorinating agent can be added to the water to minimise chlorine levels. Open the vaccine bottle under water and dissolve thoroughly in a 1 litre vessel half full, and stir well before mixing with more water. As the concentrated vaccine is slightly viscous, care should be taken to empty the bottle and its top completely by rinsing them in water. Then add water until 1 litre in the same recipient. Vaccine must be stirred thoroughly for several minutes at each stage. Do not split large bottles to vaccinate more than 1 house or drinking system, as this leads to mixing errors.
As a guide apply diluted vaccine to fresh water at ≤ 25 °C at the rate of 1 litre of drinking water per 1,000 birds per day of age for up to 7 weeks old chicks; for 7-8 week old chicks: 25-35 litres of water per 1,000 birds and for 16-20 week old birds: 35-40 litres of water per 1,000 birds. Use water meter recordings for the previous day to accurately determine the correct quantity of water in each case. Low fat skimmed milk powder (i.e. <1 % fat) should be added to the water (2-4 grams per litre) or skimmed milk (20-40 ml per litre of water) to increase the stability of the vaccine. All tubing should be emptied of plain water, so that the drinkers contain only water with vaccine.
Allow water in the drinkers to be consumed so that levels prior to vaccine application are minimal. If water is still present, the lines must be drained before applying the vaccine. The vaccine treated water should be applied within 3 hours. It should be ensured that all birds drink during this period. Birds drinking behaviour varies. It may be necessary to withhold drinking water on some sites prior to vaccination in order to ensure that all birds drink during the vaccination period. The aim is to give every bird one dose of vaccine. A period of thirst of up to 2-3 hours before vaccination may be necessary to achieve this.
Bell drinkers are preferred during first days of life, the use of nipple drinkers for one day old chickens can only be recommended if used according to national regulations.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

There were no undesired effects after application of the 10-fold dose.

4.11 Withdrawal period(s)

Meat and offal: 28 days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for aves, domestic fowl, live bacterial vaccines, salmonella
ATCvet code: QI01AE01

To stimulate active immunity to *S.* Enteritidis, phage type 4. The vaccine strain is a natural metabolic drift mutant, i.e. is it lacks or does not express certain metabolic pathways which result in attenuation. The genetic basis results in defective ribosomal protein S12 affecting polypeptide synthesis (streptomycin resistance) and defective RNA polymerase affecting transcription of DNA to RNA (rifampicin resistance).
The vaccine strain also has attenuations that increase the permeability of the cell membrane for harmful agents such as detergents and antibiotics. This means the strain has poor survival in the environment and is highly sensitive to fluoroquinolones and unlike field strains is sensitive to erythromycin.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Skimmed milk
Sucrose
Gelatin
HEPES buffer
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medical product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after dilution in water according to directions: 3 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

20 ml colourless glass bottles of hydrolytic glass type I with 1000 doses or 2000 doses. They are closed with bromobutyl rubber stoppers and sealed with aluminium caps.

Package sizes:
Cardboard box with 1 bottle (20 ml) of 1000 doses
Cardboard box with 1 bottle (20 ml) of 2000 doses
Card board box with 10 bottles (20 ml) of 2000 doses
Plastic box with 10 bottles (20 ml) of 1000 doses
Plastic box with 10 bottles (20 ml) of 2000 doses

Not all package 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 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 01708/4611

9. DATE OF FIRST AUTHORISATION

03 July 2018

10. DATE OF REVISION OF THE TEXT

October 2022

Approved 05 October 2022