

FOR ANIMAL USE ONLY

NOBILIS® GUMBORO D78

Reg. No. G2483 (Act 36/1947)

Namibia Reg. No. V98/24.3/667 NS0

INDICATIONS

Nobilis® Gumboro D78 is a live freeze-dried vaccine for the immunisation of chickens against Infectious Bursal Disease (Gumboro).

COMPOSITION

Nobilis® Gumboro D78 is a live freeze-dried vaccine containing live Infectious Bursal Disease (Gumboro) virus strain D78 with stabilisers. Each dose contains at least $4,0 \log^{10}$ TCID₅₀ of Infectious Bursal Disease (Gumboro) virus strain D78. The freeze-dried vaccine pellet contains stabilisers and gentamycin.

STORAGE

- Store in the dark between 2 °C and 8 °C.
- Do not freeze.
- Avoid prolonged or repetitive exposure to high ambient temperatures, following withdrawal from the refrigerator prior to use.
- Protect from exposure to direct sunlight.

WARNINGS

- Vaccinate healthy chickens only.
- It is advisable to vaccinate all the susceptible chickens on the farm at the same time.
- If this is not feasible, strict separation of vaccinated and unvaccinated chickens should be done to prevent the spread of the vaccine virus to the unvaccinated chickens.
- Do not mix **Nobilis® Gumboro D78** with other vaccines.
- Use according to the number of doses as indicated on the label.
- Do not open and reconstitute the vaccine until ready to start vaccination.
- Use **Nobilis® Gumboro D78** immediately after reconstitution.
- Do not store partially used vaccine vials for future use.
- Destroy any empty containers as well as unused, reconstituted vaccine and vaccination equipment according to local waste disposal regulations after completion of vaccination.
- KEEP OUT OF REACH OF CHILDREN, UNINFORMED PERSONS AND ANIMALS.
- Although this vaccine has been extensively tested under a large variety of conditions, failure thereof may ensue as a result of a wide range of reasons. If this is suspected, seek veterinary advice and notify the registration holder.

PRECAUTIONS

- Ensure that the vaccination equipment (spray apparatus, droppers) is clean prior to use.
- The spray apparatus should be free from sediments, corrosion and traces of disinfectants. It should be used for vaccination purposes only.
- Avoid contamination with traces of disinfectants or spirits.
- If the drinking water or spray method is used for administration of the vaccine, ensure that there is no iron, chlorine or disinfectants in the water.
- Ensure that the vaccine medicated water is consumed within 1 to 2 hours.
- Each vial should be used immediately after opening.
- The reconstituted vaccine should be consumed within 1 to 2 hours (i.e. shelf life of 2 hours) at a temperature of 25 °C or lower.
- Wash and disinfect the hands and equipment after vaccination.

- It is good vaccination practice to avoid contact with the eyes, hands and clothing when handling the vaccine.

DIRECTIONS FOR USE - USE ONLY AS DIRECTED

A. Spray method

Open the freeze-dried vaccine under water.

The vaccine should be dissolved in cool, clean, non-chlorinated water which is free from iron. Stir or shake the vaccine solution and administer the vaccine. The spray apparatus should be free from sediments, corrosion and traces of disinfectants (to be used for vaccination purposes only).

The vaccine-medicated water should be spread evenly over the correct number of chickens, at a distance of 30 to 40 cm, preferably when chickens are sitting together in dim light.

The vaccine should be dissolved in water in a quantity of 1 000 doses/l of water.

B. Intranasal/Eye Drop Instillation

Open the vial and dissolve the vaccine in Intervet Diluent Oculo/Nasal.

Administer the vaccine by means of a standardised dropper (usually 30 ml/1 000 doses). One drop should be applied from a height of a few centimetres onto 1 nostril or 1 eye. As an eye drop application, the drop should be allowed to spread evenly across the surface of the eye.

Do not release the chicken until a swallowing motion is noticed.

For numbers of chickens between standard dosages, the next higher dosage should be chosen.

C. Drinking water

Open the freeze-dried vaccine under water.

The vaccine should be dissolved in cool, clean, non-chlorinated water which is free from iron. Stir or shake the vaccine solution and administer the vaccine.

Ensure the uptake of all vaccine-medicated water in 2 hours. Ensure that the chickens are thirsty by withholding normal water supply from the chickens for 1 to 2 hours, depending on the ambient temperature. Ensure that there are enough drinkers available to ensure that all chickens have access to the vaccine-medicated water within 1 to 2 hours. Ensure that the water troughs are thoroughly cleaned prior to use. These should be clean and free from traces of detergents and disinfectants.

The quantity of water to be used depends on a large number of factors including ambient temperature, stocking densities, etc. It is advisable to consult water consumption tables. An example of dosing rates is as follows:

Dissolve 1 000 doses in as many litres of water as the age of the chickens in days, to a maximum of 40 litres. The vaccine should be given in the early morning as this is the main drinking period, as well as the cooler period of the day. When vaccinating large flocks, it is advisable to start by dissolving only part of the vaccine. If the vaccine is administered through a central water supply or proportioner, greater care should be taken.

For numbers of chickens between standard dosages, the next higher dosage should be chosen.

VACCINATION PROGRAMME

Nobilis® Gumboro D78 may be administered to chickens between 7 to 28 days of age. Strain D78 is effective in the face of the maternally derived antibody level usually existing in flocks between 7 to 28 days of age. The optimum time of vaccination depends on the level of the maternally derived antibody level. In case the antibody level is very variable it is advised to vaccinate the chickens twice with an interval of 1 week.

Nobilis® Gumboro D78 may be safely administered to 1-day-old chicks with no or a low level of maternal antibodies.

The optimum time and method of administration depends largely upon the local situation. Therefore, the advice of a veterinary surgeon should be sought.

IMMUNITY

The first signs of the antibody response are observed the first week after vaccination.

VACCINATION REACTION

Post-vaccination reactions have not been observed after the vaccination of healthy chickens.

PRESENTATION

Glass vials containing 1 000, 2 500 and 5 000 doses respectively and packed in cardboard boxes.

REGISTRATION HOLDER

Intervet South Africa (Pty) Ltd.
20 Spartan Road, Spartan
1619, RSA
Tel: +27 (0) 11 923 9300
Fax: +27 (0) 11 392 3158
www.msd-animal-health.co.za

MANUFACTURER

Intervet International B.V.
35 Wim de Körverstraat
Boxmeer, The Netherlands

DATE OF PUBLICATION OF THIS PACKAGE INSERT

25 July 2012

Zimbabwe Reg. No. E94/80.23.17/9446 Pharmacological classification: 802317 Distribution category: VMGD
--