FOR ANIMAL USE ONLY

NOBILIS® REO+IB+G+ND

Reg. No. G2564 (Act 36/1947) Namibia Reg. No. V05/24.3/47 NS0

Newcastle disease is a notifiable disease in terms of the Animal Diseases Act (Act35/1984). The occurrence of suspicion of this disease has to be reported to the responsible state Veterinarian.

INDICATIONS

Nobilis® Reo+IB+G+ND is a combined inactivated vaccine for chickens and is recommended for the booster vaccination of breeding stock for protection against Infectious Bronchitis and Newcastle Disease and for the immunisation against Reo Virus Infection and Infectious Bursal Disease virus so as to protect the offspring against Reo virus Infections and Gumboro Disease by maternal antibodies for at least the first week of life.

COMPOSITION

Each dose of **Nobilis**® **Reo+IB+G+ND** contains inactivated Infectious Bronchitis virus Massachusetts serotype strain 41 inducing $\geq 6,0 \log_2 HI$ units, Newcastle Disease virus Clone $30 \geq 50 \text{ PD}_{50}$ units, Gumboro virus strain D78 inducing $\geq 14,5 \log_2 VN$ units and Reo virus strains 1733 and 2408 inducing $\geq 5,0 \log_2 VN$ units. The viruses were grown in embryonated eggs or on CEF or Vero Cell cultures, inactivated with formalin and subsequently suspended in the aqueous phase of an oil adjuvant emulsion.

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

- Withdrawal period: Do not market chickens for slaughter purposes for at least 6 weeks after vaccination.
- Avoid intravenous injection.
- Ensure that chickens marketed do not have swellings at the site of vaccine administration, as this may result in the condemnation of the chickens.
- Do not mix Nobilis® Reo+IB+G+ND with other vaccines.
- Vaccination of chickens in production may lead to a slight decrease in egg production.
- Accidental self-vaccination may lead to severe local allergic reaction. Consult a physician informing him/her that the vaccine contains a mineral oil.
- Do not store partially used vaccine containers for future use and use the entire contents once opened.
- Opened bottles, not used within 3 hours, should be destroyed as well as all empty vaccine containers and vaccination equipment according to local waste disposal regulations.
- 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

- · Vaccinate healthy chickens only.
- Observe aseptic precautions. Ensure that all vaccination equipment (needles, syringes, etc.) are clean and sterile prior to and during use.
- It is essential to adhere to the vaccination programme to maintain a satisfactory immune status.

• 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

Shake well before use and at regular intervals during the vaccination process.

RECOMMENDED VACCINATION PROGRAMME

Nobilis® Reo+IB+G+ND should be given to chickens around 16 to 20 weeks of age, but not less than 4 weeks before the expected onset of lay.

For an optimal booster effect, the chickens must be primed with a live vaccine against Infectious Bronchitis, Newcastle Disease, Avian Reo virus infection and Infectious Bursal Disease.

The best results will be obtained if vaccination with inactivated vaccine takes place 6 or more weeks after administration of the live primer, but under no circumstances should it be done earlier than 4 weeks after priming.

DOSAGE AND ADMINISTRATION

- Each chicken should be given 0,5 ml of the vaccine intramuscularly into the thigh or breast muscle or subcutaneously into the lower part of the neck. (Administration via intramuscular injection into the breast muscle, the needle should be pointed in the direction of the chicken's head, to prevent the needle from entering the body cavity.)
- Shake well before use and at regular intervals during the vaccination process.
- Remove the aluminium over seal and the vaccine is ready for use.
- Inject all the chickens in the flock.

IMMUNITY

If priming and subsequent vaccination have been carried out correctly, the chickens will develop antibodies at a level which provides protection against Newcastle Disease and production losses caused by the Massachusetts serotype of Infectious Bronchitis. Under normal field situations, the offspring hatched at any stage of the laying period will have sufficient maternal antibodies to protect them against disease caused by Gumboro infections and Reo infections during the first weeks of life.

VACCINATION REACTIONS

In healthy chickens, no clinical reaction to the vaccination will be observed. For some weeks after vaccination a slight swelling may be felt at the site of the vaccination. Local tissue reactions may occur.

PRESENTATION

Bottles containing 500 ml sufficient for 1 000 doses packed in an outer cardboard carton.

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

20 January 2015

Zimbabwe Reg. No. E96/80.23.17/9437 Pharmacological classification: 802310

Distribution category: VMGD

