

FOR ANIMAL USE ONLY

NOBILIS® ND C2

Reg. No. G2872 (Act 36/1947)

Namibia Reg. No. V05/24.3/455 NS0

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

INDICATIONS

Nobilis® ND C2 is a live freeze-dried vaccine, indicated for the primary vaccination of chickens at 1 day of age or older against Newcastle Disease.

COMPOSITION

Each dose of **Nobilis® ND C2** contains at least 10^6 EID₅₀ of live, attenuated Newcastle Disease virus (NDV) strain C2. The virus is propagated in specific pathogen free eggs.

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 vaccinate within 21 days of slaughter.
- Accidental contact of **Nobilis® ND C2** with human eyes could lead to a transient conjunctivitis.
- Immunisation with **Nobilis® ND C2** alone will not provide sufficient protection against virulent Newcastle Disease.
- **Nobilis® ND C2** should be used as a primary vaccination in 1-day old chickens to reduce the severity of reactions experienced when more virulent Newcastle Disease vaccine strains are subsequently used.
- It is advisable to vaccinate all susceptible chickens on the farm at the same time. If this is not feasible, strict separation of vaccinated and non-vaccinated chickens should be done, to prevent the spread of **Nobilis® ND C2** virus to the unvaccinated chickens.
- Protect the reconstituted vaccine from direct sunlight.
- Dispose of any unused vaccine 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.
- Do not mix **Nobilis® ND C2** with other vaccines.
- Use according to the number of doses as indicated on the label.
- Use the entire contents of vial once opened.
- If the spray method is used for the administration of **Nobilis® ND C2**, ensure that there is no iron, chlorine or disinfectants in the water.
- All containers used for reconstitution and administration of **Nobilis® ND C2**, must be clean and free from rust and traces of detergents and disinfectants.
- Do not use the contents of damaged vials.
- It is good vaccination practice when handling vaccines to avoid contact with the eyes, hands and clothing.
- Wash and disinfect hands and equipment after vaccination.

- Observe aseptic precautions. Ensure that all vaccination equipment is clean and sterile prior to use.
- Do not store partially used containers for future use.

DIRECTIONS FOR USE - USE ONLY AS DIRECTED

Do not open and reconstitute **Nobilis® ND C2** until ready to start vaccination.
Reconstituted vaccine should be used within 3 hours after reconstitution.

ADMINISTRATION

Nobilis® ND C2 may be administered by spray or eye drop application.

A. Spray Method

- **Nobilis® ND C2** should be dissolved in cool, clean, non-chlorinated water which is free from iron. The vials of freeze-dried vaccine should be opened under water. The spray apparatus should be free from sediments, corrosion and traces of disinfectants (dedicated for use for vaccination purposes only).
- The vaccine medicated water should be sprayed evenly over the correct number of chickens, at a distance of 30 to 40 cm, preferably when the chickens are sitting together in dim light.
- Dissolve 1 000 doses per 250 mL to 500 mL of water and set the nozzle to produce fine droplets falling like fine rain.

B. Eye Drop Application

- Dissolve **Nobilis® ND C2** in Diluent Oculo-Nasal (or physiological saline solution) and administer by means of standardised dropper (usually 30 mL per 1 000 doses). The drop should be allowed to spread evenly across the surface of the eye. The diluent contains a dye (patent blue) which allows an easy check on the correct vaccination.
- Do not release the chicken until a swallowing motion is noticed.

VACCINATION PROGRAMME

Nobilis® ND C2 is safe for use as a primary vaccination from 1 day of age onwards. The optimum time and method of the first administration and revaccination with a secondary vaccine depends largely upon the local situation. Therefore, the advice of a veterinary surgeon should be sought.

IMMUNITY

Duration and intensity of the immune reaction and the establishment of a solid immunity are dependent on the possible presence of maternal antibodies and in general on the health and condition of the chickens. Hygiene and management are also important in the post vaccination period.

PRESENTATION

Vials containing 1 000, 2 500 and 10 000 doses.

REGISTRATION HOLDER

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MANUFACTURER

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SLEGS VIR DIEREGEBRUIK

NOBILIS® ND C2

Reg. Nr. G2872 (Wet 36/1947)

Namibië Reg. Nr. V05/24.3/455 NS0

INDIKASIES

Nobilis® ND C2 is 'n lewende gevriesdroogde entstof wat aangedui word vir die primêre inenting van hoenders vanaf 1 dag oud of ouer teen Newcastlesiekte.

SAMESTELLING

Elke dosis van **Nobilis® ND C2** bevat ten minste 10^6 EID₅₀ van lewende, verswakte Newcastlesiekte virus stam C2. Die virus word in spesifiek patogeenvrye eiers voorberei.

BERGING

- Berg in die donker tussen 2 °C en 8 °C.
- Moenie vries nie.
- Vermy lang en herhaalde blootstelling aan hoë omgewingstemperature nadat die entstof uit die yskas gehaal is voor gebruik.
- Beskerm teen blootstelling aan direkte sonlig.

WAARSKUWINGS

- **Onttrekkingsperiode:** Moenie binne 21 dae voor slagting inent nie.
- Toevallige kontak van **Nobilis® ND C2** met menslike oë mag lei tot 'n verbygaande oogvliesontsteking.
- Immunisering met **Nobilis® ND C2** alleenlik sal nie genoeg beskerming teen virulente Newcastlesiekte verleen nie. **Nobilis® ND C2** moet gebruik word as 'n primêre inenting in 1-dag oue kuikens om die graad van reaksies van daaropvolgende, meer virulente Newcastlesiekte entstofstamme te verminder.
- Dit word aanbeveel dat alle hoenders op die plaas terselfdertyd ingeënt word. As dit nie moontlik is nie, moet die ingeënte hoenders streng apart gehou word van die nie-ingeënte hoenders. Sodoende sal die verspreiding van die entstofvirus na die nie-ingeënte hoenders verhoed word.
- Beskerm hersaamgestelde entstof teen direkte sonlig.
- Vernietig alle leë entstofhouers, ongebruikte produk asook weggooibare inentingstoestelle in ooreenstemming met plaaslike afvalbestuursregulasies.
- HOU BUITÉ BEREIK VAN KINDERS, ONINGELIGTE PERSONE EN DIERE.
- Alhoewel hierdie entstof onder 'n wye verskeidenheid toestande getoets is, mag dit faal as gevolg van verskeie redes. Indien dit vermoed word, raadpleeg 'n veearts en verwittig die registrasiehouer.

VOORSORGMAATREëLS

- Slegs gesonde hoenders mag ingeënt word.
- Moenie **Nobilis® ND C2** met ander entstowwe meng nie.
- Gebruik volgens die aantal dosisse soos op die etiket aangedui.
- Die totale inhoud moet gebruik word as die flessie eers oopgemaak is.
- As die sproeimetode vir die toediening van **Nobilis® ND C2** gevolg word, moet daar seker gemaak word dat daar geen chloor of ontsmettingsmiddels in die water is nie.
- Al die houers wat gebruik word vir die hersamestelling en toediening van **Nobilis® ND C2** moet skoon en vry van roes, reinigings- en ontsmettingsmiddels wees.
- Moenie die inhoud van beskadige flessies gebruik nie.
- Dit is goeie inentingspraktyk om kontak met die oë, hande en klere te vermy wanneer die entstof hanteer word.
- Was en ontsmet die hande en toerusting na inenting.
- Aseptiese voorsorgmaatreëls moet getref word. Verseker dat inentingstoerusting skoon en steriel is voor gebruik.
- Gedeeltelik gebruikte entstofhouers moenie vir toekomstige gebruik bewaar word nie.

GEBRUIKSAANWYSINGS - GEBRUIK SLEGS SOOS AANGEDUI

Moenie **Nobilis® ND C2** oopmaak of hersaamstel totdat gereed is om met inenting te begin nie.

Hersaamgestelde entstof moet binne 3 ure gebruik word.

TOEDIENING

Nobilis® ND C2 mag deur sproei- of oogdruppelaanwending toegedien word.

A. Sproeimetode

- **Nobilis® ND C2** moet in koel, skoon, chloorvrye water, wat vry is van yster, opgelos word. Die flessies moet onder water oopgemaak word. Die sproeitoerusting moet vry wees van afskakels, roes en ontsmettingsmiddels (dit moet alleenlik vir inentingsdoeleindes gebruik word).
- Die entstogemedikeerde water moet eweredig oor die korrekte aantal hoenders, op 'n afstand van 30 tot 40 cm gespuit word. Die hoenders moet verkieslik bymekaar in dowie lig sit.
- Los 1 000 dosisse in 250 mL tot 500 mL water op en stel die sproeikop om fyn druppeltjies, wat soos fyn reën sal val, te gee.

B. Oogdruppeltoediening

- **Nobilis® ND C2** moet in Intervet Diluent Oculo-Nasal (of fisiologiesesout oplossing) opgelos word.
- Toediening deur middel van 'n gestandaardiseerde drupper (gewoonlik 30 mL per 1 000 dosisse).
- Die druppel moet toegelaat word om oor die hele oppervlakte van die oog te sprei.
- Die oplosmiddel bevat 'n kleurstof (patent blue) wat die kontrolering van die korrekte inenting vergemaklik.
- Moenie die hoender loslaat voordat daar nie 'n slukbeweging waargeneem is nie.

INENTINGSPROGRAM

Nobilis® ND C2 is veilig vir primêre inenting vanaf 1-dag oud.

Die optimale tyd en metode van die eerste toediening en herinenting met 'n sekondêre entstof hang grootliks van plaaslike toestande af. Dit is daarom nodig om advies van 'n veearts te bekom.

IMMUNITEIT

Die duur en intensiteit van die immuunreaksie asook die vestiging van 'n vaste immuniteit, is afhanglik van die moontlike teenwoordigheid van moederteenliggaampies en in die algemeen van die gesondheid en kondisie van die hoenders. Higiëne en bestuur in die na-inentingsperiode is ook belangrik.

AANBIEDING

Flessies wat onderskeidelik 1 000, 2 500 en 10 000 dosisse bevat.

REGISTRASIEHOUER

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