

FOR ANIMAL USE ONLY

NOBILIS® SG 9R

Reg. No. G2523 (Act 36/1947)

Namibia Reg. No. V05/24.3/454 NS0

INDICATIONS

A live, freeze-dried vaccine for the active immunisation of healthy layers as an aid in the control of *Salmonella gallinarum* (chicken typhoid).

COMPOSITION

Nobilis® SG 9R is a live freeze-dried vaccine based on the *Salmonella gallinarum* strain 9R. The freeze-dried pellet contains a stabiliser. Each 0,2 ml dose contains at least 2×10^7 CFU of *Salmonella gallinarum* strain 9R.

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.
- Nobilis® Diluent FD: Store at room temperature between 20 °C and 25 °C prior to use.

WARNINGS

- Initial vaccination should be carried out at 6 weeks of age.
- The use of antibiotics or other substances with a systemic action should be avoided from 7 days before vaccination until 14 days after vaccination.
- It is advisable to vaccinate all the susceptible chickens on the farm at the same time. If this is not feasible, strict separation of the vaccinated and the unvaccinated chickens should be done to prevent the spread of the vaccine organisms to the unvaccinated chickens.
- Rough pathogenic field strains, where isolated, can interfere with diagnostic tools for differentiation of *S. gallinarum* field strains from the vaccine strain.
- The vaccine strain may be isolated for a prolonged period of time from post-mortem material depending on the health status of the chickens.
- For optimal development of immunity, it is recommended not to introduce chickens to an infected environment until 14 days after primary vaccination.
- Do not open and reconstitute the vaccine until ready to start vaccination.
- Use the vaccine immediately after reconstitution and each vial must be used within 2 hours after reconstitution.
- Do not store partially used containers for future use and dispose of any unused, reconstituted vaccine, empty vaccine containers, vaccination equipment, etc. according to local waste disposal regulations after the completion of the vaccination.
- Use according to the number of doses as indicated on the label.
- Accidental injection of a bystander or self-vaccination may lead to severe local reaction, seek medical advice immediately and make this package insert available to the doctor.
- Wash and disinfect hands and equipment after 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

- Only healthy chickens should be vaccinated.
- Observe aseptic precautions. Ensure that all vaccination equipment (needles, syringes, etc.) are clean and sterile prior to use.
- The vaccination equipment should be free from traces of disinfectant and spirits.
- Ensure that all equipment is kept clean and sterile during use.
- Avoid intravenous injection.
- It is good vaccination practice when handling the vaccine to avoid contact with eyes, hands and clothes.

DIRECTIONS FOR USE - USE ONLY AS DIRECTED

Dosage and Administration

- Reconstitute the vaccine with Nobilis® Diluent FD.
- Each chicken should receive 0,2 ml of the reconstituted vaccine, subcutaneously into the lower part of the back of the neck.
- Shake the vaccine before use and at regular intervals during the vaccination process.
- Use the reconstituted vaccine within 2 hours after reconstitution.
- Inject all the chickens in the flock.

Vaccination Programme

Initial vaccination should be carried out at 6 weeks of age.
Revaccination at intervals of 12 weeks is recommended.

PRESENTATION

Cardboard boxes containing 10 vials of 1 000 doses each.

REGISTRATION HOLDER

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

MANUFACTURER

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SLEGS VIR DIEREGBRUIK

NOBILIS® SG 9R

Reg. Nr. G2523 (Wet 36/1947)

Namibië Reg. Nr. V05/24.3/454 NSO

INDIKASIES

'n Lewende, gevriesdroogde entstof vir die aktiewe immunisering van gesonde lêhoenders as 'n hulpmiddel in die beheer van *Salmonella gallinarum* (hoendertifus).

SAMESTELLING

Nobilis® SG 9R is 'n lewende gevriesdroogde entstof gebaseer op die *Salmonella gallinarum* stam 9R. Die gevriesdroogde pilletjie bevat 'n stabiliseerder. Elke 0,2 ml dosis bevat ten minste 2×10^7 CFU van die *Salmonella gallinarum* stam 9R.

BERGING

- Berg in die donker tussen 2 °C en 8 °C.
- Moenie vries nie.
- Raklewe: 12 maande as dit tussen 2 °C en 8 °C geberg word.
- Vermy langdurige en herhaalde blootstelling aan hoë omgewingstemperature nadat die entstof uit die yskas gehaal is voor gebruik.
- Beskerm teen direkte sonlig.
- Nobilis® Diluent FD: Berg teen kamertemperatuur tussen 20 °C en 25 °C voor gebruik.

WAARSKUWINGS

- Aanvanklike inenting moet op 'n ouderdom van 6 weke uitgevoer word.
- Die gebruik van antibiotika of ander middels met 'n sistemiese werking moet vermy word 7 dae voor tot 14 dae na inenting.
- Dit word aanveveel dat al die vatbare hoenders op die plaas gelyktydig ingeënt word. As dit nie moontlik is nie, moet die ingeënte hoenders streng apart van die ongeënte hoenders gehou word om te verhoed dat die entstof organismes na die oningeënte hoenders versprei.
- Wanneer onafgewerkte patogeniese veldstamme geïsoleerd is, kan dit inmeng met die diagnostiese middels vir differensiasie van *S. gallinarum* veld stamme van die entstofstam.
- Die entstofstam kan vir 'n lang tydperk geïsoleer word vanaf post-mortem materiaal afhangende van die gesondheidstatus van die hoenders.
- Vir die optimale ontwikkeling van immuniteit word dit aanbeveel dat hoenders vir ten minste 14 dae na die primêre inenting, nie aan 'n besmette omgewing blootgestel word nie.
- Moet die entstof nie oopmaak en hersaamstel voordat daar nie gereed is om met die inenting te begin nie.
- Gebruik die entstof onmiddellik na hersamestelling en elke flessie moet binne 2 uur na hersamestelling gebruik word.
- Moenie gedeeltelik gebruikte houers berg vir latere gebruik nie. Vernietig alle ongebruikte, hersaamgestelde entstof, leë entstofhouers, inentingstoerusting, ens. in ooreenstemming met plaaslike afvalbestuursregulasies, na die voltooiing van die inenting.
- Gebruik volgens die aantal dosisse soos op die etiket aangedui.

- Toevallige inspuiting van 'n omstander of self-inspuiting mag 'n ernstige lokale reaksie tot gevolg hê, verkry onmiddellik mediese hulp en stel hierdie voubiljet tot die dokter se beskikking.
- Hande en toerusting moet gewas en ontsmet word na inenting.
- HOU BUITE 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 verwitting die registrasiehouer.

VOORSORGMAATREËLS

- Slegs gesonde hoenders mag ingeënt word.
- Aseptiese voorsorgmaatreëls moet gehandhaaf word. Daar moet gesorg word dat die entstof-toerusting (naalde, spuite, ens.) skoon en steriel is voor gebruik.
- Die entstof-toerusting wat gebruik word, moet vry van spore van ontsmettingsmiddels en spiritus wees.
- Sorg dat die entstof-toerusting skoon en steriel gehou word gedurende gebruik.
- Vermy binnearse inspuiting.
- Dit is goeie inentingspraktyk wanneer entstowwe hanteer word, om kontak met die oë, hande en klere te vermy.

GEBRUIKSAANWYSINGS - GEBRUIK SLEGS SOOS AANGEDUI

Dosering en Toediening

- Die entstof moet met Nobilis[®] Diluent FD hersaamgestel word.
- Elke hoender moet 0,2 ml van die hersaamgestelde entstof, onderhuids in die laer deel van die agterkant van die nek, ontvang.
- Skud die entstof voor gebruik en met gereelde tussenposes gedurende die inentingsproses.
- Die hersaamgestelde entstof moet binne 2 uur na die hersamestelling gebruik word.
- Al die hoenders in die trop moet ingespuit word.

Inentingsprogram

Aanvanklike enting moet teen 'n ouderdom van 6 weke uitgevoer word.
Herinenting met tussenposes van 12 weke word aanbeveel.

AANBIEDING

Kartonhouers met 10 flessies wat 1 000 dosisse elk bevat.

REGISTRASIEHOUER

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