

FOR ANIMAL USE ONLY

NOBILIS® MG Inac

Reg. No. G2695 (Act 36/1947)

Namibia Reg. No. V05/24.3/58 NS0

INDICATIONS

Nobilis® Mg Inac is an inactivated vaccine for the immunisation of chickens as an aid in the prevention of airsacculitis and egg production losses caused by *Mycoplasma gallisepticum* infection.

COMPOSITION

Nobilis® Mg Inac contains *Mycoplasma gallisepticum* organisms, strain 6/85, inactivated by thimerosal and suspended in the aqueous phase of a water-in-oil emulsion in order to enhance the stimulation of immunity.

CONTENT

Each 0,5 ml dose of **Nobilis® Mg Inac** contains at least 0,23 O.D. units (one chicken effective dose) of *Mycoplasma gallisepticum* cells.

STORAGE

- Store in the dark between 2 °C and 8 °C. Do not freeze.
- Allow the vaccine to gradually reach room temperature (20 °C to 25 °C) before use.
- 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. Ensure that chickens marketed do not have swellings at the vaccination site, as this may result in the condemnation of the chickens.
- Vaccinate only healthy chickens.
- Vaccination of chickens in production may lead to a slight decrease in egg production.
- *Avoid intravenous injection.*
- Accidental self-injection may lead to severe local allergic reaction. Consult a physician informing him/her that the vaccine contains a mineral oil.
- Opened bottles should be used within 3 hours.
- Do not store partially used containers for future use, and use entire contents once opened.
- Destroy any unused, reconstituted vaccine, empty vaccine vials, needles etc. in accordance with 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

- Observe aseptic precautions. Ensure that vaccination equipment (needles, syringes, etc.) are clean and sterile before use.
- Ensure that all equipment is kept clean and sterile during vaccination.
- Do not mix the vaccine with other vaccines.
- It is good vaccination practice when handling the vaccine to avoid contact with the eyes, hands and clothing.

DIRECTIONS FOR USE - USE ONLY AS DIRECTED

Recommended Vaccination Programme

- Chickens may be vaccinated from 3 weeks old and older.
- Do not vaccinate within 14 days before the onset of lay or during lay.

Dosage and Administration

- Allow the vaccine to gradually reach room temperature (20 °C to 25 °C) prior to use.
- Remove the aluminium overseal and the vaccine is ready for use.
- Shake the bottle prior to and at regular intervals during the vaccination process.
- Inject 0,5 ml per chicken subcutaneously into the lower part of the back of the neck.
- Inject all the chickens in the flock.
- Use a sterilised syringe and needle.

Vaccination Reactions

In healthy chickens no clinical reaction 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

500 ml, Type III glass vial or a PET-flask closed with a nitril rubber stopper and sealed with a coded aluminium cap. Each vial is packed in a cardboard box.

MANUFACTURER

Intervet International Inc.
Millsboro, Delaware
19966, USA

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

DATE OF PUBLICATION OF THIS PACKAGE INSERT

25 October 1999

Zimbabwe Reg. No. E97/80.23.17/9446 Pharmacological classification: 802317 Distribution category: VMGD
--

SLEGS VIR DIERGEBRUIK

NOBILIS® MG inac

Reg. Nr. G2695 (Wet 36/1947)

Namibië Reg. Nr. V05/24.3/58 NSQ

Zimbabwe Reg. No. E97/80.23.17/9446

Nobilis® Mg inac is 'n geïnaktiveerde entstof vir die inenting van hoenders as 'n hulpmiddel by die voorkoming van lugsakontsteking en afname in eierproduksie wat deur *Mycoplasma gallisepticum* infeksie veroorsaak word.

BERGINGSANWYSINGS

- Berg in die donker tussen 2 °C en 8 °C. Moenie vries nie.
- Laat die entstof toe om geleidelik kamertemperatuur (20 °C en 25 °C) te bereik voor gebruik.
- Vermy langdurige en herhaalde blootstelling aan hoë omgewingstemperature nadat die entstof uit die yskas gehaal is.
- Beskerm teen blootstelling aan direkte sonlig.

SAMESTELLING

Nobilis® Mg inac bevat *Mycoplasma gallisepticum* organismes, stam 6/85, wat met tiomersalaat geïnaktiveer, en in die waterfase van 'n water-in-olie emulsie gesuspendeer is, om sodoende die stimulasie van immuniteit te bewerkstellig.

INHOUD

Elke 0,5 ml dosis van Nobilis® Mg inac bevat ten minste 0,23 O.D. eenhede (1 hoender effektiewe dosis) lewende *Mycoplasma gallisepticum* selle.

WAARSKUWINGS

Onttrekkingsperiode

Hoenders moet vir ten minste 6 weke na inenting, nie vir slagdoeleindes bemark word nie. Daar moet gesorg word dat hoenders wat bemark word nie swellings by die plek van entstof-toediening het nie aangesien dit tot gevolg mag hê dat die hoenders afgekeur word.

- Slegs gesonde hoenders mag ingeënt word.
- Vernietig alle ongebruikte, hersaamgestelde entstof, leë entstofhouers, naalde ens. soos voorgeskryf deur plaaslike afvalbestuursregulasies, na voltooiing van inenting.
- Gedeeltelik gebruikte houers moet nie vir latere gebruik gebêre word nie en die hele inhoud moet gebruik word as die entstof eers oopgemaak is.
- Oopgemaakte bottels moet binne 3 ure gebruik word.
- Inenting van hoenders in produksie mag 'n geringe afname in eierproduksie tot gevolg hê.
- *Vermy binnearse inspuiting.*
- Toevallige self-inspuiting mag 'n ernstige plaaslike allergiese reaksie tot gevolg hê. Raadpleeg 'n geneesheer en deel hom/haar mee dat die entstof 'n mineraalolie bevat.
- **HOU BUIE DIE 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.

VOORSORGMATREËLS

- Aseptiese voorsorgmaatreëls moet nagekom word. Daar moet verseker word dat al die inentingstoerusting (bv. naalde, spuite, ens.) skoon en steriel is voor gebruik.
- Sorg dat alle toerusting skoon en steriel gehou word gedurende gebruik.
- Die entstof moet nie met ander entstowwe gemeng word nie.
- Dit is goeie inentingspraktyk, om kontak met die oë, hande en klere te vermy wanneer entstowwe hanteer word.

GEBRUIKSAANWYSINGS

GEBRUIK SLEGS SOOS AANGEDUI.

Voorgestelde Inentingsprogram

- Hoenders mag vanaf 3 weke oud en ouer ingeënt word.
- Moenie binne 14 dae voor of gedurende die lêperiode inent nie.

Dosering en Toediening

- Laat die entstof toe om geleidelik kamertemperatuur (20 °C en 25 °C) te bereik voor gebruik.
- Verwyder die aluminiumseël en dan is die entstof gereed vir gebruik.
- Skud die bottel voor, en met gereelde tussenposes gedurende die inentingsproses.
- Spuit 0,5 ml per hoender onderhuids, in die laer deel van die agterkant van die nek, in.
- Alle hoenders in die trop moet ingespuut word.
- Gebruik 'n gesteriliseerde spuit en naald.

Inentingsreaksies

By gesonde hoenders sal geen kliniese reaksies tot die inenting waargeneem word nie. Vir 'n aantal weke na inenting mag 'n geringe swelling by die plek van inenting gevoel word. Plaaslike weefselreaksies mag voorkom.

AANBIEDING

500 ml, Tipe III glasflessie of 'n PET-fles toegemaak met 'n nitriël rubberprop en verseël met 'n gekodeerde aluminiumdoppie. Elke flessie word verpak in 'n kartonhouer.

VERVAARDIGER

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

REGISTRASIEHOUER

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

DATUM VAN PUBLIKASIE VAN DIE VOUBILJET

25 Oktober 1999