

## FOR ANIMAL USE ONLY

### NOBILIS® REO INAC

Reg. No. G2577 (Act 36/1947)

Namibia Reg. No. V05/24.3/187 NS0

**Nobilis® Reo Inac** is an inactivated vaccine recommended for the booster vaccination of primed breeding stock against Avian Reo virus in order to protect the offspring of the vaccinated chickens against Avian Reo virus infections.

### COMPOSITION

**Nobilis® Reo Inac** is an inactivated vaccine containing 2 immunogenic strains of Reo virus.

### CONTENTS

Each dose of **Nobilis® Reo Inac** contains Reo virus strains 1733 and 2408 inducing  $> 5,0 \log_2$  VN units. The viruses have been grown on CEF cell cultures and are 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.
- Allow the vaccine to reach room temperature (20 °C and 25 °C) gradually before use.
- Avoid prolonged or repetitive exposure to high ambient temperatures following withdrawal from the refrigerator prior to use.
- Protect from 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 site of vaccine administration, as this may result in the condemnation of the chickens.
- Vaccination of chickens in production may lead to a slight drop in egg production.
- Do not mix **Nobilis® Reo Inac** with other vaccines.
- Accidental self-vaccination may lead to severe local allergic reaction. Consult a physician informing him/her that the vaccine contains a mineral oil.
- **Nobilis® Reo Inac** should be protected from exposure to direct sunlight.
- Do not store partially used containers for future use and use the entire contents when opened.
- Destroy any unused vaccine and dispose of all empty vaccine containers, according to local waste disposal regulations, after vaccination.
- KEEP OUT OF REACH OF CHILDREN AND UNINFORMED PERSONS.
- 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 use.
- Ensure that all equipment is kept clean and sterile during vaccination.

- Avoid intravenous injection.
- 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**

Shake the bottle well before use.

#### **Recommended Vaccination Programme**

- **Nobilis® Reo Inac** should be given to chickens around 16 to 20 weeks of age, but not within 4 weeks prior to the onset of lay.
- For an optimal booster effect, the chickens must be primed with the live vaccine against Avian Reo virus.
- The best results will be obtained if vaccination with inactivated vaccine takes place 6 or more weeks after administration of the live primer but in no circumstances should it be done earlier than 4 weeks after priming.

### **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 well prior to and at regular intervals during the vaccination process.
- Inject 0,5 ml per chicken subcutaneously into the lower part of the neck or intramuscularly into the thigh or chest muscle. (Intramuscular injection into the chest muscle. The needle should be pointed in the direction of the chicken's head to prevent the needle from entering the body cavity).
- Inject all the chickens in the flock.
- Use a sterile syringe and needle.

### **Immunity**

When priming and subsequent vaccination have been carried out correctly the offspring born at any stage of the laying period up to 50 weeks of age will, under normal field situations, have sufficient maternal antibodies to protect them against disease caused by 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 250 ml (sufficient for 500 doses) and 500 ml (sufficient for 1 000 doses). Each bottle is packed in a cardboard carton.

### **REGISTRATION HOLDER**

Intervet South Africa (Pty) Ltd  
Reg. No. 1991/006580/07  
20 Spartan Road  
Spartan, 1619

### **DATE OF PUBLICATION OF THIS PACKAGE INSERT**

27 October 1998

Slegs vir Dieregebruik

Nobilis® Reo inac.

Reg. No. G 2577 Wet 36/1947

Namibia Reg. No. N-SR 1236

Nobilis® Reo inac. is 'n geïnaktiveerde entstof wat aanbeveel word as 'n skragingsinenting vir voorafgeënte teelhoenders teen Voël Reo virus om die nageslag van die ingeënte hoenders teen Voël Reo virus infeksies te beskerm.

#### Berging

Berg in die donker tussen 2 °C en 8 °C. Moenie vries nie.

Laat die entstof toe om geleidelik kamertemperatuur (20 °C tot 25 °C) te bereik voor gebruik.

Vermy langdurige en herhaalde blootstelling aan hoë omgewingstemperature nadat die entstof uit die yskas voorgebruik gehaal is.

Beskerm teen direkte sonlig.

#### Samestelling

Nobilis® Reo inac. is 'n geïnaktiveerde entstof wat twee immunogeniese stamme van Reovirus bevat.

#### Inhoud

Elke dosis van Nobilis® Reo inac. bevat Reovirus stamme 1733 en 2408 wat > 5,0 log<sub>2</sub> VN eenhede induseer. Die virusse is op 'n CEF sel kultuur gekweek en met formalien geïnaktiveer en daaropvolgens in die waterfase van 'n olie adjuvant emulsie gesuspendeer.

#### Waarskuwings

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

Inenting van hoenders in produksie mag 'n geringe afname in eierproduksie tot gevolg hê.

Vernietig alle ongebruikte entstof, deur bv. verbranding en vernietig ook alle entstofhouers, gebruikte naalde en spuite na inenting.

Die entstof moet teen direkte sonlig beskerm word.

Gedeeltelik gebruikte houers moet nie vir latere gebruik gebêre word nie en die hele inhoud moet gebruik word as die entstof eers oopgemaak is.

Die entstof moet nie met ander entstowe gemeng word nie.

Skud die bottel goed voor gebruik.

Toevallige self-inenting mag 'n ernstige plaaslike allergiese reaksie tot gevolg hê.

Raadpleeg 'n geneesheer en deel hom/haar mee dat die entstof 'n mineraal olie bevat.

Hou buite bereik van kinders en oningeligte persone.

Alhoewel hierdie entstof breedvoerig onder 'n wye verskeidenheid van toestande getoets is, mag dit faal as gevolg van verskeie redes. Indien dit vermoed word, raadpleeg 'n veearts en verwittig die registrasiehouer.

#### Voorsorgmaatreëls

Net gesonde hoenders mag ingeënt word.

Aseptiese voorsorgmaatreëls moet nagekom word. Daar moet verseker word dat alle entstoftoerusting (bv. naalde, spuite ens.) skoon en steriel is voor gebruik.

Sorg dat alle toerusting skoon en steriel gehou word gedurende inenting.

Vermyn binnearese inspuiting.

Dit is noodsaaklik om by die inentingsprogram te hou om sodoende 'n bevredigende immuunstatus te verseker.

Dit is goeie inentingsgebruik wanneer entstowwe gehanteer word, om kontak met die oë, hande en klere te vermy.

#### Gebruiksaanwysings

Gebruik alleenlik soos aangedui.

#### Voorgestelde Inentings Program

Nobilis® Reo inac. behoort aan hoenders om en by 16 tot 20 weke van ouderdom, maar nie binne 4 weke voor die begin van die lê periode toegedien te word.

Vir optimale onderskragings effek moet die hoenders met 'n lewendige entstof teen Voël Reo virus vooraf geënt word.

Die beste resultate sal verkry word as die inenting met inaktiewe entstof plaasvind 6 of meer weke na die toediening van die lewendige primêre inenting maar onder geen omstandighede moet dit vroeër as 4 weke na primêre inenting gedoen word nie.

#### Dosering en Toediening

Laat die entstof toe om geleidelik kamertemperatuur (20 °C tot 25 °C) te bereik voor gebruik.

Verwyder die aluminium borseël en die entstof is gereed vir gebruik.

Skud die bottel goed voor en met gereelde tussenposes gedurende die inentingsproses.

Spruit 0,5 ml per hoender onderhuids in die laer deel van die nek in of binnespiers in die dy of borsspier. (Binnespiers inspuiting in die borsspier Die naald moet in die rigting van die hoender se kop gerig word om sodoende te verhoed dat die naald die liggaamsholte binnedring).

Al die hoenders in die trop moet ingespuit word.

#### Immunititeit

As prieming en die daaropvolgende inenting reg uitgevoer was, sal die nageslag wat teN enige tyd gedurende die lêperiode uitbroei tot op ouderdom van 50 weke, onder normale veldtoestande, genoegsame moeder teen liggampies hê om hulle teen siekte, wat deur Reo infeksies veroorsaak word, gedurende die eerste week van lewe, te beskerm.

3.

#### Inentingsreaksies

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

Aanbieding

Bottels bevattende 250 ml (genoeg vir 500 dosisse) en 500 ml (genoeg vir 1000 dosisse). Elke bottel word in 'n kartonhouer verpak.

Registrasiehouer

Intervet South Africa (Edms) Bpk

Reg. No. 1991/006580/07

Spartanweg 20

Spartan, 1619

Datum van Publikasie van hierdie Voubiljet 27/10/1998

BOX LABEL / HOUER ETIKET

MAIN PANEL/HOOFPANEEL

For Animal Use Only/Slegs vir Dieregebruik

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Reg. No. G 2577 Act/Wet 36/1947

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#### Contents/Inhoud

Each dose of Nobilis® Reo inac. contains Reo virus strains 1733 and 2408 inducing  $> 5,0 \log_2$  VN units. The viruses have been grown on CEF cell cultures and are inactivated with formalin and subsequently suspended in the aqueous phase of an oil adjuvant emulsion.

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#### Storage/Berging

Store in the dark between 2 °C and 8 °C. Do not freeze.

Berg in die donker tussen 2 °C and 8 °C. Moenie vries nie.

For full particulars, see the enclosed package insert.

Vir volle besonderhede, sien die ingeslote voubiljet.

250 ml (sufficient for 500 doses/genoeg vir 500 dosisse) or/of

500 ml (sufficient for 1000 doses/genoeg vir 1000 dosisse).

#### Registration Holder/Registrasiehouer

Intervet South Africa (Pty) Ltd/(Edms) Bpk

Reg. No. 91/065807

20 Spartan Road/Weg

Spartan, 1619

N.B. This pack must be sold as a unit. Do not break or open seal prior to sale.

L.W. Hierdie verpakking moet as 'n eenheid verkoop word. Moenie die seël breek of oopmaak voor verkoop nie.

SIDE PANEL/SYPANEEL

Batch Number/Lot Nommer  
Expiry Date/Vervaldatum

BOTTLE LABEL/BOTTEL ETIKET

For Animal Use Only/Slegs vir Dieregebruik

Nobilis® Reo inac.

Reg. No. G 2577 Act/Wet 36/1947  
Namibia Reg. No. N-SR 1236

For full particulars, see the enclosed package insert.  
Vir volle besonderhede, sien die ingeslote voubiljet.

1000 doses/dosisse (or of 500 doses/dosisse)

Registration Holder/Registrasiehouer  
Intervet South Africa (Pty) Ltd/(Edms) Bpk  
Reg. No. 1991/006580/07  
20 Spartan Road/Weg  
Spartan, 1619

Batch Number/Lot Nommer  
Expiry Date/Vervaldatum