

FOR ANIMAL USE ONLY

NOBILIS® IB+ND+EDS

Reg. No. G2613 (Act 36/1947)

INDICATIONS

Nobilis® IB+ND+EDS is a combined inactivated vaccine for the protection of layers and breeders against Egg Drop Syndrome '76 and for the booster vaccination of breeding chickens against Newcastle Disease and Massachusetts types of Infectious Bronchitis.

COMPOSITION

Nobilis® IB+ND+EDS contains immunogenic strains of Infectious Bronchitis virus (Massachusetts), and Newcastle Disease virus and the BC strain 14 Egg Drop Syndrome '76 virus.

Each 0,5 ml dose of **Nobilis® IB+ND+EDS** contains immunogenic strains of Infectious Bronchitis virus (Massachusetts) (inducing $\geq 6,0 \log_2$ HI units), Newcastle disease virus, (containing ≥ 50 PD₅₀ units), and BC strain 14 of Egg Drop Syndrome '76 virus (inducing $\geq 6,5 \log_2$ HI units). The viruses have been inactivated with formalin and subsequently suspended in the water phase of a water-in-oil 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 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® IB+ND+EDS** with other vaccines.
- Vaccination of chickens in production may lead to a slight drop 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 containers for future use and use the entire contents once opened.
- Opened bottles, not used within 24 hours, should be destroyed as well as empty vaccine containers and vaccination equipment according to local waste disposal regulations 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

- 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 program to maintain a satisfactory immune response.
- It is good vaccination practice when handling the vaccine to avoid contact with the eyes, hands and clothing.

DIRECTION FOR USE - USE ONLY AS DIRECTED

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

RECOMMENDED VACCINATION PROGRAMME

Nobilis® IB+ND+EDS 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 live vaccines of the separate component strains.

The best results will be obtained if vaccination with inactivated IB vaccine takes place 6 weeks or more after administering the live vaccine 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 breast muscle or subcutaneously into the back of the neck. (Intramuscular 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.)
- Allow the vaccine to gradually reach room temperature (20 °C to 25 °C) prior to use.
- 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 Egg Drop Syndrome '76, Newcastle disease and production losses caused by the Massachusetts serotype of Infectious Bronchitis.

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. This does not constitute permanent tissue damage provided the vaccination has been carried out aseptically.

PRESENTATION

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

REGISTRATION HOLDER

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Fax: +27 (0) 11 392 3158
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MANUFACTURER

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Boxmeer, The Netherlands

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SLEGS VIR DIERGEBRUIK

Nobilis® IB+ND+EDS

Reg. Nr. G2613 (Wet 36/1947)

INDIKASIES

Nobilis® IB+ND+EDS is 'n gekombineerde geïnaktiveerde entstof vir die beskerming van lê- en teelhoenders teen Eierproduksieverliessindroom '76 en 'n skragingsinenting van teelhoenders teen Newcastle siekte en Massachusetts tipe Aansteeklike Brongitis.

SAMESTELLING

Nobilis® IB+ND+EDS bevat immunogeniese stamme van Aansteeklike Brongitis virus (Massachusetts), Newcastle siekte virus en BC stam 14 van Eierproduksieverliessindroom '76 virus.

Elke 0,5 ml dosis van **Nobilis® IB+ND+EDS** bevat immunogeniese stamme van Aansteeklike Brongitis virus (Massachusetts tipe) (induseer $\geq 6,0 \log_2$ HI eenhede), Newcastle siekte virus (bevattende $\geq 50 \text{ PD}_{50}$ eenhede), en BC stam 14 Eierproduksieverliessindroom '76 virus (induseer $\geq 6,5 \log_2$ HI eenhede). Die virusse is geïnaktiveer met formalien en daaropvolgens in die water fase van 'n water-in-olie emulsie gesuspendeer.

BERGING

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

WAARSKUWINGS

- **Onttrekkingsperiode:** Moenie hoenders bemark vir slagting vir ten minste 6 weke na inenting nie.
- Vermoed binnearese inspuiting.
- Daar moet gesorg word dat hoenders wat bemark word, nie swellings by die plek van inenting het nie, aangesien dit die afkeuring van die hoenders tot gevolg mag hê.
- Moenie **Nobilis® IB+ND+EDS** met ander entstowwe meng nie.
- Inenting van hoenders in produksie mag 'n geringe afname in eierproduksie tot gevolg hê.
- Toevallige self-inenting mag 'n ernstige plaaslike allergiese reaksie ten gevolg hê. Raadpleeg 'n geneesheer en deel hom/haar mee dat die entstof 'n mineraal olie bevat.
- Gedeeltelik-gebruikte houers moet nie vir latere gebruik gebêre word nie en die hele inhoud moet gebruik word as die entstof eers oopgemaak is.
- Oop bottels wat nie binne 24 uur gebruik is nie moet saam met alle leë entstoffessies asook inentings toerusting vernietig word volgens plaaslike afvalbestuursregulasies.
- **HOU BUIE BEREIK VAN KINDERS, ONINGELIGTE PERSONE EN DIERE.**
- Alhoewel hierdie entstof breedvoerig 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

- Slegs gesonde hoenders mag ingeënt word.
- Aseptiese voorsorgmaatreëls moet nagekom word. Daar moet verseker word dat alle entstof-toerusting (bv. naalde, spuite ens.) skoon en steriel is voor en tydens gebruik.
- 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 SLEGS SOOS AANGEDUI

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

VOORGESTELDE INENTINGS PROGRAM

Nobilis® IB+ND+EDS moet aan hoenders toegedien word op ongeveer 16 tot 20 weke oud, maar nie minder as 4 weke voor die begin van die lê periode nie.

Vir optimale skragings effek, moet die hoenders met lewende entstof teen Aansteekele Brongitis, en Newcastle siektes gepriem word.

Die beste resultate word verkry as die inenting met geïnaktiveerde Aansteekele Brongitis (IB) entstof 6 weke of meer na die lewende entstof toegedien word maar onder geen omstandighede moet dit vroeër as 4 weke na prieming gedoen word nie.

DOSERING EN TOEDIENING

- Spuit 0,5 ml per hoender onderhuids in die agterkant van die nek of binnespier in die borsspier. (Binnespierse 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).
- Die entstof moet toegelaat word om geleidelik kamertemperatuur (20 °C tot 25 °C) te bereik voor gebruik.
- Skud die bottel voor en met gereelde tussenposes gedurende die inentingsproses.
- Verwyder die aluminium beseël en die entstof is gereed vir gebruik.
- Alle hoenders in die trop moet ingespuut word.

IMMUNITEIT

As die inenting en die prieming reg uitgevoer word, sal die hoenders teen liggaampies ontwikkel op 'n vlak wat beskerming teen Eierproduksieverliesindroom '76, Newcastle siekte en produksieverliese veroorsaak deur die Massachusetts serotipe van Aansteekele Brongitis sal verleen.

INENTINGS REAKSIES

By gesonde hoenders sal geen kliniese reaksies tot die inenting waargeneem word nie. Vir 'n aantal weke na inenting mag 'n geringe swelling op die plek van inenting gevoel word. Hierdie swelling veroorsaak nie permanente beskadiging van die weefsel nie, op voorwaarde dat die inenting asepties uitgevoer was.

AANBIEDING

Bottels van 500 ml wat voldoende is vir 1 000 dosisse, verpak in 'n kartonhouer.

REGISTRASIEHOUER

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VERVAARDIGER

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