FOR ANIMAL USE ONLY

Nobilis® IB PRIMO QX
Reg. No. G4211 (Act 36/1947)

Only for use by or under the supervision of persons registered in terms of or authorised in terms of section 23 (1) (c) of the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982).

INDICATIONS
For the active immunisation of chickens from 1 day of age or older to reduce clinical signs of disease caused by infection with Infectious Bronchitis Virus serotype D388/QX.
Onset of immunity: 3 weeks
Duration of immunity: 8 weeks

COMPOSITION
Each dose of reconstituted vaccine contains:
Live Avian Infectious Bronchitis Virus strain D388: $\geq 10^{4,0}$ EID_{50}[1]
[1]EID_{50} = 50 % Egg Infective Dose

STORAGE
Vaccine: Store between 2 °C and 8 °C. Do not freeze. Protect from light.
Solvent: Store between 2 °C and 25 °C. Do not freeze.

CONTRA-INDICATIONS
None

ADVERSE REACTIONS
Vaccination may induce a mild transient respiratory reaction lasting a few days, which may depend on the health and condition of the birds.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

WARNINGS
- **Withdrawal period:** Meat: 21 days. Eggs: Not to be used in chickens that lay eggs for human consumption. The safety of **Nobilis® IB Primo QX** has not been established during lay, eggs must not be used for human consumption.
- Vaccination may induce a mild transient respiratory reaction lasting a few days, depending on the health and condition of the chickens.
- If you notice any serious effects or other effects not mentioned in this package insert, please inform your veterinarian.
- 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.
- In case of spray administration, personal protective equipment consisting of masks with eye protector should be worn when handling **Nobilis® IB Primo QX**.
- Observe aseptic precautions.
- Ensure that the vaccination equipment (spray apparatus, droppers) is clean prior to use.
- It is good vaccination practice when handling the vaccine to avoid contact with the eyes, hands and clothing.
- Avoid contamination with traces of disinfectant or spirits.
- Destroy any unused, reconstituted vaccine and empty vaccine containers in accordance with local waste disposal regulations after completion of the vaccination.

- Wash hands after vaccination.

DIRECTIONS FOR USE - USE ONLY AS DIRECTED

DOSAGE

After reconstitution administer at least 1 dose of the vaccine per chicken by coarse spray or intranasal/ocular administration (eye drop) to chickens from 1 day of age or older.

Spray method

- The vaccine should be dissolved in cool, clean, non-chlorinated water which is free from iron.
- The spray apparatus should be free from sediments, corrosion and traces of disinfectants.
- The spray apparatus should be used for vaccination purposes only.
- Measure the correct volume of water for the number of chickens to be vaccinated and add the contents of the correct number of cups while stirring. Mix thoroughly with a clean stirrer, ensuring that all vaccine is dissolved.
- Offer to the chickens immediately after reconstitution.
- When spray devices are used it is advisable to consult the technical staff of Intervet SA before using this technique.

Oculo-nasal administration

- Reconstitute the vaccine with the appropriate amount of a suitable solvent and administer by means of the standardised dropper.
- One drop should be applied into one nostril or one eye. Ensure that the nasal drop is inhaled before freeing the chicken. The eye drop should be allowed to spread across the surface of the eye and do not release the chicken until a swallowing motion is noticed.
- Nobilis® Diluent Oculo Nasal is available as solvent.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Nobilis® IB Ma5. No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except for the product mentioned above. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

PRESENTATION

Lyophilisate

Sealed aluminium laminated cups containing 1 000, 5 000 or 10 000 doses.

Solvent (oculo-nasal administration)

35 mℓ Plastic vial with a rubber stopper and aluminium cap.

Packaging

Ten cups of lyophilisate containing the same dosage.
Ten vials of solvent (only supplied with 1 000 doses of vaccine).
Not all pack sizes may be marketed.

REGISTRATION HOLDER

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MANUFACTURER

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5831 AN Boxmeer, The Netherlands

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SLEGS VIR DIEREGEBRUIK

Nobilis® IB Primo QX
Reg. Nr. G4211 (Wet 36/1947)

Slegs vir gebruik deur of onder die toesig van persone wat geregistreer of goedgekeur is in terme van Afdeling 23(1)(c) van die Wet op Veterinêre en Para-Veterinêre Beroepe, 1982 (Wet Nr. 19 van 1982).

INDIKASIES
Vir die aktiewe immunisering van hoenders vanaf ‘n ouderdom van 1 dag en ouer om kliniese tekens van die siekte wat veroorsaak word deur infeksie met Aansteeklike Brongitisvirus serotipe D388/QX te verminder.
Aanvang van immuniteit: 3 weke
Duur van immuniteit: 8 weke

KONTRA-INDIKASIES
Geen

SAMESTELLING
Elke dosis hersaamgestelde entstof bevat:
Lewende Hoender Aansteeklike Brongitisvirus stam D388: > $10^{4,0}$ EID_{50}[1]
[1] EID_{50} = 50 % Eier Infektiewe Dosis

BERGING
Entstof: Berg tussen 2 °C en 8 °C. Moenie vries nie. Beskerm teen lig.
Oplosmiddel: Berg tussen 2 °C en 25 °C. Moenie vries nie.

WAARSKUWINGS
- **Onttrekkingsperiode:**
  Vleis: 21 dae
  Eiers: Moenie in hoenders gebruik wat eiers vir menslike verbruik lê nie.
- Inenting mag 'n ligte, verbygaande respiratoriese reaksie veroorsaak wat 'n paar dae duur, afhangende van die gesondheid en kondisie van die hoenders.
- As u enige ernstige reaksies of enige ander reaksies waarneem wat nie in hierdie voubiljet genoem is nie, kontak asseblief u veearts.
- HOU BUITE DIE 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.

VOORSORGMAATREëLS
- Slegs gesonde hoenders mag ingeënt word.
- Wanneer **Nobilis® IB Primo QX** hanteer word in die geval van die sproeimetode moet veiligheidstoerusting wat uit maskers met ‘n oogskerm bestaan, gedra word.
- Aseptiese voorsorgmaatreëls moet nagekom word.
- Daar moet gesorg word dat alle inentingstoerusting (sproeitoerusting, druppers) skoon is voor gebruik.
- Dit is goeie inentingspraktyk wanneer entstowwe hanteer word, om kontak met die oë, hande en klere te vermy.
- Vermy besmetting met spore van ontsmettingmiddels en spiritus.

- Vernietig alle ongebruikte, hersaamgestelde entstof, leë entstofhouers, naalde ens. soos voorgeskryf deur plaaslike afvalbestuursregulasies, na voltooiing van inenting.
- Was hande na inenting.

GEBRUIKSAANWYSINGS - GEBRUIK SLEGS SOOS AANGEDUI.

DOSIS
Na die hersamestelling van die entstof, dien ten minste 1 dosis per hoender deur die growwe sproeimetode of deur oogdruppel- of neusdruppeltoediening aan hoenders vanaf ‘n ouderdom van 1 dag of ouer toe.

Sproeimetode
- Die entstof moet in koel, skoon water wat vry van chloor en yster is opgelos word.
- Die sproeitoerusting moet vry van afsaksels, roes en spore van ontsmettingsmiddels wees.
- Die sproeitoerusting moet slegs vir inentingsdoeleindes gebruik word.
- Meet die korrekte volume water vir die aantal hoenders wat ingeënt moet word af en voeg die inhoud van die korrekte aantal koppies by terwyl geroer word. Meng deeglik met 'n skoon roerstafie om te verseker dat al die entstof opgelos is.
- Gee onmiddellik vir die hoenders na hersamestelling.
- Wanneer sproeitoerusting gebruik word, is dit raadsaam om die tegniese personeel van Intervet SA te raadpleeg voor die metode gebruik word.

Oogdruppel-/neusdruppeltoediening
- Meng die entstof met die regte hoeveelheid geskikte oplosmiddel, en dien toe deur middel van ‘n gestandardiseerde drupper.
- Een druppel moet in een neusgat of een oog toegedien word. Maak seker dat die neusdruppel ingeasem word voordat die hoender vrygelaat word. Nobilis® Diluent Oculo Nasal is beskikbaar as ‘n oplosmiddel.

INTERAKSIE MET ANDER MEDISINALE PRODUKTE EN ANDER VORMS VAN INTERAKSIES
Veiligheids- en doeltreffendheidsdata is beskikbaar wat bewys dat die entstof gemeng en toegedien kan word saam met Nobilis® IB Ma5. Geen inligting is beskikbaar oor die veiligheid en doeltreffendheid van die entstof wanneer dit saam met enige ander geneesmiddels behalwe die bogenoemde produk gebruik word nie. Die besluit om die entstof voor of na enige ander geneesmiddel te gebruik moet vir elke geval individueel bepaal word.

AANBIEDING
Liofilisaat
Verseëlde aluminium gelamineerde koppies met 1 000, 5 000 of 10 000 dosisse.
Oplosmiddel (Oogdruppel-/neusdruppeltoediening)
35 mℓ Plastiekflessie met 'n rubberproppie en aluminiumdoppie.
Verpakking
Tien koppies liofilisaat met dieselfde dosis.
Tien flessies van die oplosmiddel (slegs voorsien saam 1 000 dosisse van die entstof).
Nie alle verpakkingsgroottes word bemark nie.

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