

FOR ANIMAL USE ONLY
Consult a veterinarian before use

BLU-VAX

FOR SHEEP
Reg. No. G4534 (Act 36/1947)

Bluetongue is a notifiable disease in terms of the Animal Diseases Act (Act No. 35 of 1984) and any suspicion or confirmation of the disease must be reported to the responsible state veterinarian immediately.

INDICATIONS

BLU-VAX is an inactivated adjuvanted polyvalent bluetongue virus (BTV) vaccine, formulated as an emulsion, for the active immunisation of healthy sheep against bluetongue disease.

COMPOSITION PER DOSE (1 mL)

BLU-VAX is an oil emulsion vaccine containing inactivated serotypes of the bluetongue virus (BTV). BTV serotypes included in the formulation consists of serotypes 1, 2, 3, 4, 5, 7, 12, 13, 16, 17 and 24. Each dose (1 mL) of vaccine contains $\geq 1 \times 10^8$ TCID₅₀ per serotype.

STORAGE INSTRUCTIONS

Store and transport refrigerated (between 2 °C to 8 °C). Protect from light. Do not freeze. Do not use this veterinary vaccine after the expiry date which is stated on the container label. Use immediately after opening. **Do not store any vials into which a needle or other device has been inserted, for future use.**

WARNINGS

- **WITHDRAWAL PERIOD:** DO NOT SLAUGHTER ANIMALS FOR HUMAN CONSUMPTION WITHIN 21 DAYS OF VACCINATION.
- Vaccinate healthy animals only.
- Do NOT mix with any other vaccine or immunological product. No information is available on the compatibility of **BLU-VAX** with any other vaccine or medication.
- Care should be taken to avoid direct contact with the product and self-injection or eye or skin contamination. **If contact occurs, rinse affected area repeatedly with clean water.**
- Medical advice should be sought in the event of accidental exposure.
- Do not over- or under-dose the vaccine.
- Usually no marked reaction follows vaccination, although a transient swelling may appear at the site of inoculation and some animals may show a moderate rise of temperature for one or two days.
- Ensure that marketed animals do not have local reactions (swellings) at the site of vaccine administration, or elevated temperature reactions (fever) as this may result in the condemnation of the carcasses.
- Use the entire contents of a vial once opened.
- Do not use in animal species other than those indicated.
- Do not administer to animals in poor or extremely poor body condition.
- Do not inject intravenously.
- **KEEP THE PRODUCT OUT OF REACH OF CHILDREN, UNINFORMED PERSONS AND ANIMALS.**
- Although this product 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 and Registrar.

PRECAUTIONS

- Observe aseptic precautions. Ensure that all vaccination equipment (containers, syringes and needles) are clean and sterile prior to and during use.
- Do not use the contents of damaged vials.
- Wash and disinfect hands with a disinfectant after vaccination.
- Wear protective clothing, masks, gloves etc. according to hazard standards.

- Avoid contact of the product with skin, eyes and mouth.
- Do not eat, drink or smoke whilst handling the product.
- Destroy any unused vaccine and dispose of all vaccine containers and disposable equipment after use, in accordance with the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008).
- Do not contaminate rivers, dams or any water sources with containers or waste.

Local reactions may occur in some animals at the injection site. They will disappear after a few days. If you notice any serious effects not mentioned in this leaflet, please inform your veterinarian.

DIRECTIONS FOR USE

- **Use only as directed.**
- It is normal for **BLU-VAX** to develop a cream layer on top during storage. **Simple inversion of the vial prior to injection is adequate to remix all the components.**
- Inject sheep subcutaneously, on the side of the neck only. DO NOT deviate from the recommended route and injection site location.
- Ensure that all animals are vaccinated.
- It is essential to adhere to the vaccination schedule to maintain a satisfactory immune response.
- This inactivated vaccine is safe for use in ewes during all stages of pregnancy and newborn lambs born from unvaccinated ewes.
- Animals must receive a complete full vaccination schedule before the period of highest risk associated with bluetongue outbreak.
- Annual revaccination of all animals prior to the outbreak season is recommended.
- Vaccination with **BLU-VAX** allows targeted use in the face of an outbreak or in case of perceived immediate threat of infection.

DOSAGE

- Inject 1 dose (1 mL) subcutaneously, on the side of the neck only.
- A booster vaccination of 1 mL is recommended after 3 to 4 weeks.

Annual revaccination with a single dose (1 mL), 2 months prior to the outbreak season, is recommended.

PRESENTATION

BLU-VAX, a white to light-pink emulsion, is presented in pack sizes of 20 mL and 100 mL high density polyethylene (HDPE) vials of natural colour, capped with a gold-coloured aluminium cap with two-bridge tabs, labelled and packed in a product-specific outer cardboard carton.

REGISTRATION HOLDER

Vetvax (Pty) Ltd
Reg. No. M2004/035302/07
442 Rigel Avenue South
Erasmusrand, Pretoria, 0181
Tel: +27 (0) 12 349 2772

MANUFACTURER

Design Biologix CC
Reg. No. 1992/028856/23
Tel: +27 (0) 12 349 2772
www.designbio.co.za

SLEGS VIR DIERGEGBRUIK
Raadpleeg 'n veearts voor gebruik

BLU-VAX

VIR SKAPE
Reg. Nr. G4534 (Wet 36/1947)

Bloutong is 'n aanmeldbare dieresiekte kragtens die Wet op Dieresiektes (Wet Nr. 35 van 1984). Enige vermoede of bevestigde gevalle van die siekte moet onmiddellik aan die verantwoordelike staatsveearts gerapporteer word.

INDIKASIES

BLU-VAX is 'n geïnaktiveerde adjuvant polivalente bloutongvirus (BTV) entstof, geformuleer as 'n emulsie, vir die aktiewe immunisering van gesonde skape teen bloutong.

SAMESTELLING PER DOSIS (1 mL)

BLU-VAX is 'n olie-emulsie entstof wat geïnaktiveerde serotipes van die boutongvirus (BTV) bevat. BTV serotipes wat tydens formulering bygevoeg word sluit in serotipes 1, 2, 3, 4, 5, 7, 12, 13, 16, 17 en 24. Elke dosis (1 mL) van die entstof bevat $\geq 1 \times 10^5$ TCID₅₀ per serotipe.

BERGINGSAAWYSINGS

Bêre in 'n yskas en verkoel tydens vervoer (tussen 2 °C en 8 °C). Beskerm teen lig. Moenie vries nie. Moenie hierdie veeartsenykundige entstof gebruik na die vervaldatum wat op die verpakking aangedui is nie. Gebruik onmiddellik nadat die flessie oopgemaak is. **Moenie flessies waarin 'n naald of ander toestel aangebring is, vir toekomstige gebruik bêre nie.**

WAARSKUWINGS

- **ONTTREKKINGSPERIODE:** MOENIE DIERE BINNE 21 DAE NA INENTING VIR MENSLIKE GEBRUIK SLAG NIE.
- Slegs gesonde diere moet ingeënt word.
- MOENIE met enige ander entstof of immunologiese produk meng nie. Geen informasie is beskikbaar in verband met die verenigbaarheid van **BLU-VAX** met enige ander entstof of medisyne nie.
- Voorsorg moet getref word om direkte kontak met die produk, self-inspuiting, of kontaminasie van die oë of vel te voorkom. **Indien kontak plaasvind, spoel die geaffekteerde area herhaaldelik met skoon water af.**
- Verkry mediese advies in die geval van toevallige blootstelling aan die produk.
- Moenie die entstof oor- of onderdoseer nie.
- Normaalweg volg geen merkbare reaksie na inenting nie, alhoewel kortstondige swelling op die plek van inenting kan voorkom en sommige diere 'n matige styging in temperatuur vir een of twee dae kan toon.
- Verseker dat diere wat bemark word geen lokale reaksies (swelling) by die entstof toedieningsplek of verhoogde liggaamstemperatuur (koorsreaksie) toon nie, aangesien dit kan lei tot afkeur van karkasse.
- Gebruik die volle inhoud van 'n flessie sodra dit oopgemaak word.
- Moenie in diere anders as die aangeduide spesies gebruik word nie.
- Moenie toegedien word aan diere in 'n swak of uiters swak liggaamskondisie nie.
- Moenie binnears toegedien word nie.
- **HOU DIE PRODUK BUITE BEREIK VAN KINDERS, ONINGELIGTE PERSONE EN DIERE.**
- Alhoewel hierdie produk breedvoerig onder 'n wye verskeidenheid van toestande getoets is, mag dit vaal as gevolg van verskeie redes. Indien vermoed word dat die produk gefaal het, raadpleeg 'n veearts en verwittig die registrasiehouer en die Registrateur.

VOORSORGMATREËLS

- Volg standaard steriele prosedures tydens toediening van inspuitings. Verseker dat alle entstoftoerusting (houers, spuitende en naalde) skoon en steriel is voor en tydens gebruik.
- Moenie die inhoud van beskadigde flessies gebruik nie.

- Was en ontsmet hande met 'n ontsmettingsmiddel na enting van diere.
- Dra beskermende klere, maskers en handskoene, ens. in lyn met die standaarde vir gevaarlike middels.
- Vermoedige kontak van die produk met die vel, oë en mond.
- Moenie eet, drink of rook tydens hantering van die produk nie.
- Vernietig enige ongebruikte entstof, en verwyder entstofhouers en entstoftoerusting na gebruik, in ooreenstemming met die Nasionale Wet op Omgewingsafval, 2008 (Wet Nr. 59 van 2008).
- Moenie riviere, damme of enige waterbronne met houers of afval besoedel nie.

Lokale reaksies mag voorkom by die inspuitingsplek van sommige diere. Dit sal verdwyn na 'n paar dae. Indien u ernstige reaksies opmerk wat nie in hierdie voorsorgaanwysing vermeld is nie, stel asseblief u veearts in kennis.

GEBRUIKSAANWYSINGS

- **Gebruik slegs soos aangedui.**
- Dit is normaal vir **BLU-VAX** om 'n romerige laag bo-op te vorm tydens berging. **Versigtige omkering van die flessie is voldoende om al die komponente weer te vermeng voor gebruik.**
- Spuit skape onderhuid, slegs aan die kant van die nek. MOENIE afwyk van die aanbevole roete en inspuitingsarea nie.
- Verseker dat alle diere ingeënt word.
- Dit is noodsaaklik om die inentingsprogram te volg om 'n bevredigende immunrespons te handhaaf.
- Hierdie geïnaktiveerde entstof is veilig vir gebruik in ooie tydens al die fases van dragtigheid asook in lammetjies gebore van ongeënte ooie.
- Diere moet 'n volledige inentingsprogram voltooi voor die periode aanbreek wat verband hou met die grootste risiko vir bloutong uitbraak.
- Jaarlikse her-inenting van alle diere word aanbeveel, voor die bloutong uitbraakseisoen.
- Enting met **BLU-VAX** bewerkstellig doelgerigte gebruik wanneer bloutong uitbraak in die gesig gestaar word of indien 'n onmiddellike bedreiging van infeksie ontstaan.

DOSIS

- Spuit 1 dosis (1 mL) onderhuid, slegs aan die kant van die nek.
- 'n Skraagdosis van 1 mL moet 3 tot 4 weke later toegedien word.

Jaarlikse her-inenting met 'n enkele skraagdosis (1 mL) word aanbeveel, 2 maande voor die risiko periode vir bloutong uitbraak aanbreek.

AANBIEDING

BLU-VAX, 'n wit tot lig-pienk emulsie, word aangebied in 'n pakgrootte van 20 mL en 100 mL hoëdigtheid-poliëteleen (HDPE) flessies van natuurlike kleur, bedek met 'n goudkleurige aluminium doppie, geëtiketeer en verpak in 'n produksiespesifieke buitenste kartonhouer.

REGISTRASIEHOUER

Vetvax (Edms) Bpk
Reg. Nr. M2004/035302/07
Rigellaan-Suid 442
Erasmusrand, Pretoria, 0181
Tel: +27 (0) 12 349 2772

VERVAARDIGER

Design Biologix BK
Reg. Nr. 1992/028856/23
Tel: +27 (0) 12 349 2772
www.designbio.co.za