

**FOR ANIMAL USE ONLY**  
Consult a veterinarian before use

## OVIVAX

FOR SHEEP AND GOATS  
Reg. No. G4552 (Act 36/1947)

### INDICATIONS

**OVIVAX** is an inactivated combination vaccine for the active immunisation of healthy sheep and goats against respiratory disease complex caused by *Mannheimia haemolytica* serotype A1, *Pasteurella multocida* serotype A, *Bibersteinia trehalosi* and Parainfluenza virus type 3 (PI-3).

### COMPOSITION PER DOSE (2 mℓ)

**OVIVAX** is a formalin-inactivated multi-component whole cell formulation containing *M. haemolytica* serotype A1 (leukotoxin), *P. multocida* serotype A, *B. trehalosi* and PI-3. Each dose (2 mℓ) of vaccine contains *M. haemolytica* serotype A1:  $\geq 4 \times 10^7$  cfu, *P. multocida* serotype A:  $\geq 1 \times 10^8$  cfu, *B. trehalosi*:  $\geq 1 \times 10^6$  cfu and Parainfluenza virus type 3:  $\geq 5 \times 10^8$  TCID<sub>50</sub> per 2 mℓ.

### STORAGE INSTRUCTIONS

Store and transport refrigerated (between 2 °C and 8 °C). Do not freeze. Protect from high temperatures and sunlight during vaccination. Do not use after the expiry date printed on the container. Use immediately after opening the vial. **Do not store any vials into which a needle or another 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 **OVIVAX** with any other vaccine or medication.
- Care should be taken to avoid direct contact with the product, 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.
- Use the entire contents of a vial once opened.
- Do not use in animal species other than those indicated.
- **OVIVAX** may be used in pregnant animals during all stages of pregnancy.
- 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) is 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 (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 package insert, please inform your veterinarian.

### DIRECTIONS FOR USE

- **Use only as directed.**
- It is normal for **OVIVAX** 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 and goats subcutaneously, on the side of the neck only. DO NOT deviate from the recommended route and injection site location.
- Sheep and goats may be vaccinated from the age of 2 months and older.
- Animals require a full vaccination program to be completed before the period of highest risk associated with pneumonia.
- Ensure that all animals are vaccinated.
- It is essential to adhere to the vaccination schedule to maintain a satisfactory immune response.
- Annual revaccination of all animals with a 2 mℓ dose prior to the highest risk period is recommended.

### DOSAGE

**Sheep and goats:** Inject 1 dose (2 mℓ) subcutaneously, on the side of the neck only. A booster vaccination of 2 mℓ should be administered after 3 to 4 weeks. Annual revaccination of all animals with a 2 mℓ dose is recommended thereafter.

### PRESENTATION

**OVIVAX**, a milky off-white to light-yellow 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. 2004/035302/07  
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 DIEREGERBRUIK

### Raadpleeg 'n veearts voor gebruik

# OVIVAX

VIR SKAPE EN BOKKE

Reg. Nr. G4552 (Wet 36/1947)

### INDIKASIES

**OVIVAX** is 'n geïnaktiveerde kombinasie-entstof vir die aktiewe immunisering van gesonde skape en bokke teen respiratoriese siekte kompleks veroorsaak deur *Mannheimia haemolytica* serotipe A1, *Pasteurella multocida* serotipe A, *Bibersteinia trehalosi* en Parainfluenza virus tipe 3 (PI-3).

### SAMESTELLING PER DOSIS (2 mL)

**OVIVAX** is 'n formalien-geïnaktiveerde multi-komponent heelsel formulering wat *M. haemolytica* serotipe A1 (leukotoksien), *P. multocida* serotipe A, *B. trehalosi* en PI-3 bevat. Elke dosis (2 mL) van die entstof bevat *M. haemolytica* serotipe A1:  $\geq 4 \times 10^7$  cfu, *P. multocida* serotipe A:  $\geq 1 \times 10^9$  cfu, *B. trehalosi*:  $\geq 1 \times 10^8$  cfu en Parainfluenza virus tipe 3:  $\geq 5 \times 10^6$  TCID<sub>50</sub> per 2 mL.

### BERGINGSAAWYSINGS

Bêre in 'n yskas en verkoel tydens vervoer (tussen 2 °C en 8 °C). Moenie vries nie. Beskerm teen hoë temperature en sonlig tydens inenting. Moenie gebruik na die vervaldatum wat op die entstofhouer gedruk is nie. Gebruik onmiddellik nadat die entstofhouer oopgemaak is. **Moenie entstofhouders 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 enige ander produk meng nie. Geen informasie is beskikbaar in verband met die gebruik van **OVIVAX** met enige ander entstof of produk nie.
- Voorsorg moet getref word om direkte kontak met die produk, self-inspuiting, of kontak 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.
- Gebruik die volle inhoud van 'n entstofhouer sodra dit oopgemaak word.
- Moenie in diere anders as die aangeduide spesies gebruik word nie.
- **OVIVAX** is veilig vir die gebruik in skape en bokke in alle trimesters van dragtigheid.
- 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 skeidenheid van toestande getoets is, mag dit faal 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 inspuittings. Verseker dat alle entstoftoerusting (houders, spuite en naalde) skoon en steriel is voor en tydens gebruik.
- Moenie die inhoud van beskadigde entstofhouders gebruik nie.
- Was en ontsmet hande met 'n ontsmettingsmiddel na enting van diere.

- Dra beskermende klere, maskers en handskoene, ens. in lyn met die standarde 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 entstofhouders en entstoftoerusting na gebruik, in ooreenstemming met die Nasionale Omgewingsbestuur: Wet op Afval (Wet 59 van 2008).
- Moenie riviere, damme of enige waterbronne met entstofhouders of afval besoedel nie.

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

### GEBRUIKSAANWYSINGS

- **Gebruik slegs soos aangedui.**
- Dit is normaal vir **OVIVAX** om 'n romerige laag bo-op te vorm tydens berging. **Versigtig omkering van die entstofhouer is voldoende om al die komponente weer te vermeng voor gebruik.**
- Spuit skape en bokke onderhuids, slegs aan die kant van die nek. MOENIE afwyk van die aanbevole roete en inspuittingsarea nie.
- Skape en bokke mag vanaf die ouderdom van 2 maande en ouer ingeënt word.
- 'n Volledige inentingsprogram moet voltooi word voor die tydperk van die hoogste risiko verbonde aan respiratoriese siekte.
- Verseker dat alle diere ingeënt word.
- Dit is noodsaaklik om die inentingsprogram te volg om 'n bevredigende immuunresponse te handhaaf.
- Jaarlikse herinenting met 'n enkel dosis (2 mL) van alle diere word aanbeveel, voor die hoogste risiko tydperk.

### DOSIS

**Skape en bokke:** Spuit 1 dosis (2 mL) onderhuids, slegs aan die kant van die nek. 'n Skraagdosie van 2 mL moet 3 tot 4 weke later toegedien word. Jaarlikse herinenting met 'n enkel dosis (2 mL) word daarna aanbeveel.

### AANBIEDING

**OVIVAX**, 'n melkerige wit tot liggeel emulsie, word aangebied in pakgroottes van 20 mL en 100 mL hoëdigtheid-poliëteleen (HDPE) entstofhouders van natuurlike kleur, bedek met 'n goudkleurige aluminium doppie, geëtiketeer en verpak in 'n produksiespesifieke buitenste kartonhouer.

### REGISTRASIEHOUER

Vetvax (Edms) Bpk  
Reg. Nr. 2004/035302/07  
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