

FOR ANIMAL USE ONLY

Consult a veterinarian before use

# Clostrivax O

## FOR SHEEP

Reg. No. G4487 (Act 36/1947)

**Clostrivax O** is an adjuvanted multi-component vaccine for the active immunisation of sheep against diseases caused by *Clostridium perfringens* type A (enterotoxaemia, gas gangrene, sudden death syndrome), *C. perfringens* type D (enterotoxaemia, pulpy kidney), *C. tetani* (tetanus), *C. novyi* type A (swelled head), *C. novyi* type B (black disease, infectious necrotic hepatitis), *C. chauvoei* (black leg, black quarter), *Bibersteinia trehalosi* (pasteurellosis, septicaemia), *C. septicum* (malignant oedema, braxy), and *Mannheimia haemolytica* type A1 (pneumonia).

### STORAGE INSTRUCTIONS

Store in a refrigerator, between 2 °C and 8 °C. Protect from light. Do not freeze. Protect from high temperatures and direct sunlight. Do not use after the expiry date printed on the packaging and container. Do not store any vials into which a needle or other device has been inserted, for future use.

### COMPOSITION

**Clostrivax O** contains toxoids from *C. perfringens* type A, *C. perfringens* type D, *C. tetani*, *C. novyi* types A and B, *C. septicum*, *M. haemolytica* type A1 leukotoxin and formalin inactivated *C. chauvoei* and *B. trehalosi* anacultures.

### WARNINGS

- **WITHDRAWAL PERIOD:** DO NOT SLAUGHTER ANIMALS FOR HUMAN CONSUMPTION WITHIN 21 DAYS OF VACCINATION.
- 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.
- Do not use in any species other than those indicated.
- Do not administer to animals in poor or extremely poor body condition.
- 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 for a wide range of reasons. If this is suspected, seek veterinary advice and notify the registration holder and the Registrar.
- Do not over- or under-dose the vaccine.
- In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
- Do not inject intravenously.

### PRECAUTIONS

- Follow standard sterile procedures during administration of injections.
- Do not mix this product with any other vaccines or medicines.
- Avoid contact of the product with skin, eyes and mouth.
- Do not eat, drink or smoke whilst handling the product.
- Do not contaminate rivers, dams or any other water sources with containers or waste.

- Dispose of all containers and all unused contents in accordance with the local law.
- Do not use disinfectants or antiseptics to sterilise any equipment.
- Wear protective clothing, masks, gloves, etc. according to hazard standards.
- Adhere to the vaccination programme to obtain optimum results.

Due to the adjuvant used, 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.
- Shake gently before use by inverting the vial several times.
- Use sterile needles and syringes to administer **Clostrivax O**.
- Inject sheep subcutaneously, on the side of the neck. DO NOT deviate from the recommended route and injection site location.
- Lambs may be vaccinated from two months of age and older.
- **Clostrivax O** is safe to use in ewes in all trimesters of pregnancy or lambs nursed by pregnant ewes.
- Ewes sensitised within the last 12 months should be vaccinated 2-6 weeks before lambing is due to commence. This provides passive protection to the lamb, via colostrum, for up to 8 weeks.

### DOSAGE

- Inject 2 ml via the subcutaneous route, on the side of the neck.
- A booster vaccination of 2 ml should be administered 3 to 4 weeks later. Annual revaccination is recommended thereafter.

### PRESENTATION

**Clostrivax O**, a light brown to amber liquid with an off-white sediment if left to settle, is presented in a pack size of a 100 ml and 500 ml high density polyethylene (HDPE) vial 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

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### MANUFACTURER

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# Clostrivax O

## VIR SKAPE

Reg. Nr. G4487 (Wet 36/1947)

**Clostrivax O** is 'n adjuvant multi-komponent entstof vir die aktiewe immunisering van skape teen siektes wat veroorsaak word deur *Clostridium perfringens* tipe A (enterotoksemie, gasgangreen, skielike dood sindroom), *C. perfringens* tipe D (enterotoksemie, bloednier), *C. tetani* (klem-in-die-kaak), *C. novyi* tipe A (dikkop), *C. novyi* tipe B (aansteeklike nekrotiese hepatitis), *C. chauvoei* (sponssiekte), *Bibersteinia trehalosi* (pasteurellose, septisemie), *C. septicum* (kwaadaardige eedem), en *Mannheimia haemolytica* tipe A1 (respiratoriese siekte).

### BERGINGSANWYSINGS

Bêre in 'n yskas, tussen 2 °C en 8 °C. Beskerm teen lig. Moenie vries nie. Beskerm teen hoë temperatuur en direkte sonlig. Moenie gebruik na die vervaldatum wat op die verpakking en houer gedruk is nie. Moenie houers waarin 'n naald of ander toestel aangebring is, vir toekomstige gebruik bêre nie.

### SAMESTELLING

**Clostrivax O** bevat toksioëde van *C. perfringens* tipes A en D, *C. tetani*, *C. novyi* tipes A en B, *C. septicum*, *M. haemolytica* tipe A1 leukotoksien en formalien-geïnaktiveerde *C. chauvoei* en *B. trehalosi* anakulture.

### WAARSKUWINGS

- **ONTREKKINGSPERIODE:** MOENIE DIERE BINNE 21 DAE NA INENTING VIR MENSLIKE GEBRUIK SLAG NIE.
- Normaalweg volg geen merkbare reaksie op inenting nie, alhoewel 'n kortstondige swelling op die plek van inenting kan voorkom, en sommige diere 'n matige styging in temperatuur vir een of twee dae kan toon.
- Moenie in spesies anders as die aangeduide spesies gebruik nie.
- Moenie toegedien word aan diere in 'n swak of uiters swak liggaamskondisie nie.
- HOU DIE PRODUK BUITE BEREIK VAN KINDERS, ONINGELIGTE PERSONE EN DIERE.
- Alhoewel hierdie produk breedvoerig onder 'n wye verskeidenheid toestande getoets is, mag dit vaal as gevolg van verskeie redes. Indien dit vermoed word, raadpleeg 'n veearts en verwittig die registrasiehouer en die Registrateur.
- Moenie die entstof onder- of oordoseer nie.
- In geval van toevallige self-inspuiting, verkry onmiddellik mediese advies en verskaf die inhoud van hierdie voubiljet of die etiket aan die geneesheer.
- Moenie via die intravenese roete toedien nie.

### VOORSORGMATREËLS

- Volg standaard steriele prosedures tydens toediening van inspuittings.
- Moenie hierdie produk met enige ander entstof of medisyne meng nie.
- Vermoë kontak van die produk met die vel, oë en mond.
- Moenie eet, drink of rook tydens die hantering van die produk nie.
- Moenie riviere, damme of waterbronne met houers of afval besoedel nie.
- Gooi alle lêë houers en alle ongebruikte inhoud volgens die plaaslike wetgewing weg.

- Moenie ontsmettingsmiddels of antiseptika gebruik om enige toerusting te steriliseer nie.
- Dra beskermende klere, maskers en handskoene, ens. in lyn met die standaard vir gevaarlike middels.
- Volg die inentingsprogram om sodoende 'n bevredigende immuunrespons te verkry.

Lokale reaksies mag voorkom by die inspuittingsplek van sommige diere, as gevolg van die adjuvant (hulpmiddel) wat deel vorm van die entstof. Dit sal verdwyn na 'n paar dae. Indien 'n ernstige reaksie opmerk wat nie in hierdie voubiljet vermeld is nie, stel asseblief u veearts in kennis.

### GEBRUIKSAANWYSINGS

- Gebruik slegs soos aangedui.
- Meng die houer versigtig voor gebruik, deur dit 'n paar maal om te keer.
- Gebruik steriele naalde en spuite om **Clostrivax O** toe te dien.
- Spuit skape onderhuids, aan die kant van die nek. MOENIE van die aanbevole roete en inspuittingsplek afwyk nie.
- Lammers kan ingeënt word vanaf 'n ouderdom van 2 maande en ouer.
- **Clostrivax O** is veilig vir gebruik in oë tydens alle trimesters van dragtigheid, of by lammers wat drink aan dragtige oë.
- Oë wat binne die vorige 12 maande ingeënt was, moet 2 tot 6 weke voor lamtyd weer ingeënt word. Dit bied die lam tot 8 weke passiewe beskerming via die biesmelk.

### DOSIS

- Spuit 2 mL via die onderhuidse roete, aan die kant van die nek.
- 'n Skraagdosis van 2 mL moet 3 tot 4 weke later toegedien word. Daarna word 'n jaarlikse her-inenting aanbeveel.

### AANBIEDING

**Clostrivax O**, 'n ligbruin tot amberkleurige vloeistof met 'n wit sediment, word aangebied in 'n pakgrootte van 'n 100 mL en 500 mL hoëdigtheid-poliëteen (HDPE) flessie van natuurlike kleur, bedek met 'n goudkleurige aluminium doppie, geëtiketteer en verpak in 'n produkspesifieke buitenste kartonhouer.

### REGISTRASIEHOUER

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