FOR ANIMAL USE ONLY
Consult a veterinarian before use

CHLAMYVAX

FOR CATTLE, SHEEP AND GOATS

Reg. No. G4535 (Act 36/1947)

INDICATIONS

CHLAMYVAX is an inactivated bivalent vaccine for the active immunisation of healthy cattle, sheep and goats against enzootic abortion caused by *Chlamydia abortus* and a range of subclinical disease manifestations including infectious conjunctivitis, arthritis, infertility, enteritis, mastitis and reduced growth rates caused by *Chlamydia pecorum*.

COMPOSITION PER DOSE (1 mℓ)

CHLAMYVAX is an oil emulsion vaccine consisting of formalin-inactivated *C. abortus* and *C. pecorum* strains.

Each dose (1 mℓ) of **CHLAMYVAX** contains:
Inactivated *C. abortus*: $\geq 2{,}5 \times 10^5$ $TCID_{50}$ per 1 mℓ dose
Inactivated *C. pecorum*: $\geq 2{,}5 \times 10^5$ $TCID_{50}$ per 1 mℓ dose

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 **CHLAMYVAX** 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.**
- Accidental self-injection of the user may cause serious reactions. In case of accidental self-injection, seek medical advice immediately and show the package insert or label to the physician.
- 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.
- May be used in pregnant animals during all stages of pregnancy.
- 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) is clean and sterile prior to and during use. Use sterile equipment when administering the vaccine.
- Do not use the contents of damaged vials.
- Wash and disinfect hands with a disinfectant after vaccination.
- Do not use disinfectants or antiseptics to sterilize any equipment.
- 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.
- Use the entire contents of a vial once opened. Do not store partially used containers for future use.
- It is essential to adhere to the vaccination programme to maintain a satisfactory immune response.
- 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 **CHLAMYVAX** 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 animals 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.
- Administer a dose at least four weeks before the breeding season or during early pregnancy, before 60 days of gestation.
- **CHLAMYVAX** is safe for use during all stages of pregnancy.
- In the face of an outbreak animals may be vaccinated before lambing/calving, which reduces abortions and prevents excretion of the pathogenic micro-organism by infected pregnant animals.
- Vaccination during an outbreak also protects heifers/ewes not previously vaccinated (naïve animals) from becoming latently infected, thus resulting in fewer aborted animals for the following year.
- It is critical to vaccinate replacement heifers/ewes as well as newly purchased animals.
- **CHLAMYVAX** may be used as a therapeutic vaccine targeted at subclinical chlamydial infections caused by *C. pecorum* during high risk outbreak periods. A long-term protective effect however requires frequent revaccination.

DOSAGE

- **Cattle:** Inject 2 mℓ subcutaneously, on the side of the neck only.
- **Sheep and goats:** Inject 1 mℓ subcutaneously, on the side of the neck only.

A booster vaccination of the above mentioned doses for cattle, sheep and goats respectively is recommended 3 to 4 weeks later.

PRESENTATION

CHLAMYVAX, 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

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MANUFACTURER

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Design Biologix

SLEGS VIR DIEREGEBRUIK
Raadpleeg 'n veearts voor gebruik

CHLAMYVAX

VIR BEESTE, SKAPE EN BOKKE
Reg. Nr. G4535 (Wet 36/1947)

INDIKASIES
CHLAMYVAX is 'n geïnaktiveerde bivalente entstof vir die aktiewe immunisering van gesonde beeste, skape en bokke teen ensoötiese aborsie wat veroorsaak word deur *Chlamydia abortus*, asook 'n reeks subkliniese manifestasies van siektes insluitend aansteeklike konjunktivitis, artritis, onvrugbaarheid, enteritis, mastitis en verlaagde groeitempo wat veroorsaak word deur *Chlamydia pecorum*.

SAMESTELLING PER DOSIS (1 mℓ)
CHLAMYVAX is 'n olie-emulsie entstof wat formalien-geïnaktiveerde *C. abortus* en *C. pecorum* stamme bevat.

Elke dosis (1 mℓ) van die entstof bevat:
Geïnaktiveerde *C. abortus* ≥ 2,5 x 10^5 $TCID_{50}$ per 1 mℓ dosis
Geïnaktiveerde *C. pecorum* ≥ 2,5 x 10^5 $TCID_{50}$ per 1 mℓ dosis

BERGINGSAANWYSINGS
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
- **ONTREKKINGSPERIODE:** 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 **CHLAMYVAX** 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.**
- Toevallige self-inspuiting mag ernstige reaksies tot gevolg hê. In geval van toevallige self-inspuiting, verkry onmiddellik mediese advies en verskaf die inhoud van hierdie voubiljet of die etiket aan die geneesheer.
- 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.
- Veilig vir gebruik in dragtige diere tydens alle stadiums van dragtigheid.
- Moet nie in diere anders as die aangeduide spesies gebruik word nie.
- Moenie toegedien word aan diere in 'n swak of uiters swak liggaamskondisie nie.
- Moenie binneaars 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 faal as gevolg van verskeie redes. Indien vermoed word dat die produk gefaal het, raadpleeg 'n veearts en verwittig die registrasiehouer en Registrateur.

VOORSORGMAATREËLS
- Volg standaard steriele prosedures tydens toediening van inspuitings. Verseker dat alle entstoftoerusting (houers, spuite en naalde) skoon en steriel is voor en tydens gebruik. Gebruik steriele toerusting vir die toediening van die entstof.
- Moenie die inhoud van beskadigde flessies gebruik nie.
- Was en ontsmet hande met 'n ontsmettingsmiddel na enting van diere.
- Moenie ontsmettingsmiddels of antiseptiese middels gebruik om enige toerusting vir enting te steriliseer nie.
- Dra beskermende klere, maskers en handskoene, ens. in lyn met die standaarde vir gevaarlike middels.
- Vermy kontak van die produk met die vel, oë en mond.
- Moenie eet, drink of rook tydens hantering van die produk nie.
- Gebruik die volle inhoud van 'n flessie sodra dit oopgemaak word. Moenie ongebruikte entstof berg vir latere gebruik nie.
- Dit is belangrik om die inentingsprogram te volg om sodoende 'n optimale immuunrespons te handhaaf.
- Vernietig enige ongebruikte entstof en verwyder alle entstofhouers en weggooibare 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 voubiljet vermeld is nie, stel asseblief u veearts in kennis.

GEBRUIKSAANWYSINGS
- **Gebruik slegs soos aangedui.**
- Dit is normaal vir **CHLAMYVAX** 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 toediening.**
- Spuit beeste, skape of bokke onderhuids, slegs aan die kant van die nek. MOENIE van die aanbevole roete en inspuitingsplek afwyk nie.
- Verseker dat alle diere ingeënt word.
- 'n Entingsdosis moet toegedien word ten minste vier weke voor die teelseisoen, 60 dae voor dragtigheid of tydens vroeë dragtigheid.
- **CHLAMYVAX** is veilig vir gebruik tydens alle stadiums van dragtigheid.
- Wanneer 'n uitbraak in die gesig gestaar word, mag diere voor kalwing/lamtyd ingeënt word om sodoende aborsies te voorkom. Dit sal ook dien as voorkoming van die verspreiding van die patogeniese mikro-organisme deur geïnfekteerde weefsel van dragtige diere.
- Enting tydens 'n uitbraak voorkom ook dat verse en ooie wat nog nooit ingeënt is nie (naïewe diere) nie later van tyd besmet word nie. Dit lei dus tot minder geaborteerde diere vir die volgende jaar.
- Dit is krities belangrik om alle vervangingsdiere (verse/ooie en diere wat nuut aangekoop word) in te ent.
- **CHLAMYVAX** mag gebruik word as 'n terapeutiese entstof wat spesifiek gemik is op die subkliniese chlamydiale infeksies wat veroorsaak word deur *C. pecorum* tydens periodes wat geassosieer word met 'n hoë risiko vir uitbraak. 'n Langtermyn beskermende effek vereis dat diere gereeld her-ingeënt moet word.

DOSIS
- **Beeste:** Spuit 1 dosis (2 mℓ) onderhuids, slegs aan die kant van die nek.
- **Skape en bokke:** Spuit 1 dosis (1 mℓ) onderhuids, slegs aan die kant van die nek.

'n Skraagdosis van die bogenoemde doserings, vir beeste, skape en bokke afsonderlik, moet 3 tot 4 weke later toegedien word.

AANBIEDING
CHLAMYVAX, 'n wit tot lig-pienk emulsie, word aangebied in 'n pakgrootte van 20 mℓ en 100 mℓ hoëdigtheid-poliëtileen (HDPE) flessies van natuurlike kleur, bedek met 'n goudkleurige aluminium doppie, geëtiketeer en verpak in 'n produkspesifieke buitenste kartonhouer.

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