

PROPOSED LABEL: TRIBOVAX  
OUTER CARTON: MAIN PANEL

FOR ANIMAL USE ONLY

SLEGS VIR DIEREGERBRUIK

### TRIBOVAX

Reg. No. / Nr. xxxx Act/Wet 36/1947  
Clostridial Vaccine for Sheep and Cattle  
Klostridiale Entstof vir Skape en Beeste

For the active immunisation of Sheep and Cattle against *Clostridium perfringens* types A,B,C and D, *C. chauvoei*, *C. novyi*, *C. septicum*, *C. tetani*, *C. sordellii* and *C. haemolyticum*.

Vir die aktiewe immunisering van Skape en Beeste teen *Clostridium perfringens* tipes A,B,C en D, *C. chauvoei*, *C. novyi*, *C. septicum*, *C. tetani*, *C. sordellii* en *C. haemolyticum*.

STORE BETWEEN +2 °C AND +8 °C. PROTECT FROM LIGHT. DO NOT FREEZE.  
BERG TUSSEN + 2 °C EN + 8 °C. BESKERM TEEN LIG. MOENIE BEVRIES NIE.

#### CONTAINS/BEVAT:

	Potency value/dose Potensie waarde/dosis
<i>C. perfringens</i> type A toxoid/tipe A toxoïed	≥ 0,5 IU
<i>C. perfringens</i> type B toxoid/tipe B toxoïed	≥ 10 IU β/≥ 5 IU ε
<i>C. perfringens</i> type C toxoid/tipe C toxoïed	≥ 10 IU β
<i>C. perfringens</i> type D toxoid/tipe D toxoïed	≥ 5 IU ε
<i>C. chauvoei</i> whole culture/heel kultuur	Meets Ph. Eur.
<i>C. novyi</i> toxoid/ toxoïed	≥ 3,5 IU
<i>C. septicum</i> toxoid/ toxoïed	≥ 2,5 IU
<i>C. tetani</i> toxoid/ toxoïed	≥ 2,5 IU
<i>C. sordellii</i> toxoid/ toxoïed	≥ 1,0 U
<i>C. haemolyticum</i> toxoid/ toxoïed	≥ 10 U

(20 ml, 50 ml) 100 ml (250 ml)

FOR FULL PARTICULARS SEE ENCLOSED PACK INSERT  
VIR VOLLE BESONDERHEDE SIEN INGESLOTE VOUWILJET

#### Registration Holder/Registrasiehouer:

Intervet South Africa (Pty) Ltd  
Private Bag X2026, Isando, 1600  
Tel. No. +27 (0)11 923 9300 Fax No. +27 (0)11 974 9320

Lot No./Nr.:  
Expires/Verval:

PROPOSED LABEL: TRIBOVAX  
OUTER CARTON: SIDE PANEL/S

**DOSE**

Subcutaneous injection.

**Sheep and lambs over 2 weeks of age:**

Two injections of 1 ml each at an interval of 6 weeks, and a booster annually thereafter.

**Cows and calves over 2 weeks of age:**

Two injections of 2 ml each at an interval of 6 weeks, and a booster annually thereafter.

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**DOSIS**

Onderhuidse inspuiting.

**Skape en lammers ouer as 2 weke:**

Twee inspuitings van 1 ml elk, met 'n tussenpose van 6 weke en 'n jaarlikse skraag dosis.

**Koeie en kalwers ouer as 2 weke:**

Twee inspuitings van 2 ml elk, met 'n tussenpose van 6 weke en 'n jaarlikse skraag dosis.

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PROPOSED LABEL: TRIBOVAX  
IMMEDIATE CONTAINER

FOR ANIMAL USE ONLY

SLEGS VIR DIEREGERBUIK

### TRIBOVAX

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Clostridial Vaccine for Sheep and Cattle  
Klostridiale Entstof vir Skape en Beeste

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#### CONTAINS/BEVAT:

	Potency value/dose Potensie waarde/dosis
<i>C. perfringens</i> type A toxoid/tipe A toxoïed	≥ 0,5 IU
<i>C. perfringens</i> type B toxoid/tipe B toxoïed	≥ 10 IU β/≥ 5 IU ε
<i>C. perfringens</i> type C toxoid/tipe C toxoïed	≥ 10 IU β
<i>C. perfringens</i> type D toxoid/tipe D toxoïed	≥ 5 IU ε
<i>C. chauvoei</i> whole culture/heel kultuur	Meets Ph. Eur.
<i>C. novyi</i> toxoid/ toxoïed	≥ 3,5 IU
<i>C. septicum</i> toxoid/ toxoïed	≥ 2,5 IU
<i>C. tetani</i> toxoid/ toxoïed	≥ 2,5 IU
<i>C. sordellii</i> toxoid/ toxoïed	≥ 1,0 U
<i>C. haemolyticum</i> toxoid/ toxoïed	≥ 10 U

(20 ml, 50 ml) 100 ml (250 ml)

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PROPOSED LABEL: TRIBOVAX  
ABBREVIATED LABEL: IMMEDIATE CONTAINER

FOR ANIMAL USE ONLY

SLEGS VIR DIEREGERBUIK

**TRIBOVAX**

Reg. No. / Nr. xxxx Act/Wet 36/1947  
Clostridial Vaccine for Sheep and Cattle  
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BERG TUSSEN + 2 °C EN + 8 °C. BESKERM TEEN LIG. MOENIE BEVRIES NIE.

**(20 ml, 50 ml) 100 ml (250 ml)**

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PROPOSED PACKAGE INSERT: TRIBOVAX

<p>FOR ANIMAL USE ONLY</p> <p><b>TRIBOVAX</b> Reg. No. xxxx Act 36/1947 Clostridial Vaccine for Sheep and Cattle.</p> <p><b>STORAGE INSTRUCTIONS</b> Store between +2 °C and +8 °C. Protect from light. Do not freeze. Opened bottles should be discarded within 8 hours of opening.</p> <p><b>INDICATIONS</b> For the active immunisation of sheep and cattle from 2 weeks of age to prevent mortality, lesions and clinical signs of disease caused by <i>Clostridium perfringens</i> type A (enterotoxaemia, haemorrhagic enteritis), <i>C. perfringens</i> type B (lamb dysentery), <i>C. perfringens</i> type C (necrotic enteritis), <i>C. perfringens</i> type D (enterotoxaemia/ pulpy kidney), <i>C. chauvoei</i> (blackleg/ blackquarter), <i>C. novyi</i> type B (infectious necrotic hepatitis), <i>C. septicum</i> (malignant oedema), <i>C. tetani</i> (tetanus), <i>C. sordellii</i> (sudden death syndrome/ haemorrhagic enteritis), and <i>C. haemolyticum</i> (bacillary haemoglobinuria). Immunity is established within 14 days of administration of the second dose and lasts for one year.</p>	<p>SLEGS VIR DIEREGERBRUIK</p> <p><b>TRIBOVAX</b> Reg. Nr. xxxx Wet 36/1947 Klostridiale Entstof vir Skape en Beeste.</p> <p><b>BERGINGSAAWYSINGS</b> Berg tussen +2 °C en +8 °C. Beskerm teen lig. Moenie vries nie. Vernietig alle flesse binne 8 ure na oopmaak.</p> <p><b>AANDUIDINGS</b> Vir die aktiewe immunisering van skape en beeste van 2 weke ouderdom om sterftes, letsels en kliniese tekens van siekte veroorsaak deur <i>Clostridium perfringens</i> tipe A (enterotoksemie, rooiderm), <i>C. perfringens</i> tipe B (bloedpens), <i>C. perfringens</i> tipe C (nekrotiese enteritis), <i>C. perfringens</i> tipe D (enterotoksemie/ bloednier), <i>C. chauvoei</i> (sponssiekte), <i>C. novyi</i> tipe B (aansteeklike nekrotiese hepatitis), <i>C. septicum</i> (kwaadaardige edeem), <i>C. tetani</i> (tetanus), <i>C. sordellii</i> (skielike dood sindroom/hemorargiese enteritis), and <i>C. haemolyticum</i> (basillêre hemoglobinurie).</p> <p>Immuniteit is 14 dae na enting met die tweede dosis teweeggebring en is vir 1 jaar doeltreffend.</p>
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**COMPOSITION/SAMESTELLING**

<i>C. perfringens</i> type A toxoid/tipe A toxoïed	Potency value/dose Potensie waarde/dosis
<i>C. perfringens</i> type B toxoid/tipe B toxoïed	≥ 0,5 IU
<i>C. perfringens</i> type C toxoid/tipe C toxoïed	≥ 10 IU β/≥ 5 IU ε
<i>C. perfringens</i> type D toxoid/tipe D toxoïed	≥ 10 IU β
<i>C. chauvoei</i> whole culture/heelkultuur	≥ 5 IU ε
<i>C. novyi</i> toxoid/ toxoïed	Meets Ph. Eur.
<i>C. septicum</i> toxoid/ toxoïed	≥ 3,5 IU
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<i>C. sordellii</i> toxoid/ toxoïed	≥ 2,5 IU
<i>C. haemolyticum</i> toxoid/ toxoïed	≥ 1,0 U
	≥ 10 U

## WARNINGS

- Only vaccinate healthy animals.
- It is not recommended that other vaccines be administered within 14 days before or after vaccination with this product.
- Only sterile syringes and needles should be used. The injection should be made through an area of clean, dry skin.
- Part-used containers should be discarded at the end of the day's operations, as under field conditions it may be difficult to avoid accidental contamination. Bury or burn used containers.
- *Cattle*: Swelling may occur at the site of injection which should resolve within 1 – 2 months. The incidence and severity may be higher in calves less than one month of age.
- *Sheep*: Swelling may occur at the site of injection which should resolve within 1 – 2 months post vaccination.
- As with any vaccine occasional hypersensitivity reactions may occur. In such cases consult your veterinarian.
- Keep out of reach of children, uninfected persons and animals.
- Although this vaccine has been 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.

**DIRECTIONS FOR USE:** USE ONLY AS DIRECTED  
SHAKE WELL BEFORE AND DURING USE.

### Administration

Subcutaneous injection, preferably in the loose skin on the side of the neck.

## WAARSKUWINGS

- Ent slegs gesonde diere.
- Dit word nie aanbeveel dat ander entstowwe binne 14 dae voor of na enting met hierdie produk toegedien word nie.
- Slegs steriele spuite en naalde moet gebruik word. Die inspuiting moet in skoon, droë vel toegedien word.
- Houers wat net gedeeltelik gebruik is moet vernietig word aan die einde van die dag van gebruik, want onder veldtoestande is dit moeilik om toevallige kontaminasie van die entstof te vermy. Begrawe of verbrand gebruikte houers.
- *Beeste*: 'n Swelsel by die plek van inenting mag voorkom, maar behoort binne 1 – 2 maande te verdwyn. Die voorkoms en ernstigheid mag hoër wees in kalwers jonger as een maand oud.
- *Skape*: 'n Swelsel by die plek van inenting mag voorkom maar behoort binne 1 – 2 maande te verdwyn.
- Soos met alle entstowwe mag hipersensitiwiteitsreaksies af en toe voorkom. Raadpleeg u veearts in so 'n geval.
- Hou buite bereik van kinders, oningeligte persone en diere.
- Alhoewel hierdie entstof breedvoerig onder 'n wye verskeidenheid van toestande getoets is, mag dit faal as gevolg van verskeie redes. Indien dit vermoed word, raadpleeg 'n veearts en verwittig die registrasiehouer.

**GEBRUIKSAANWYSINGS:** GEBRUIK SLEGS SOOS AANGEDUI SKUD GOED VOOR EN GEDURENDE GEBRUIK.

### Toediening

Onderhuise inspuiting, verkieslik in die los vel op die sykant van die nek,

## Dosage

- **Sheep and lambs over 2 weeks of age**  
Two injections of 1 ml each at an interval of 6 weeks, and a booster annually thereafter.

The vaccine course should be completed at least 2 weeks before maximum immunity is required i.e. a period of risk or in pregnant ewes during lambing. Previously sensitised ewes should be injected 2 – 6 weeks before lambing is due to commence. This provides passive protection of the lamb, via the colostrum, for up to 12 weeks.

The vaccine may be used in lambs as young as two weeks of age regardless of serum antitoxin levels acquired from maternal transfer.

- **Cows and calves over 2 weeks of age**  
Two injections of 2 ml each at an interval of 6 weeks, and a booster annually thereafter.  
Previously sensitised cows should be injected 2 – 6 weeks before calving is due to commence. This provides passive protection of the calf, via the colostrums, for up to 12 weeks.  
The vaccine may be used in calves as young as two weeks of age regardless of serum antitoxin levels acquired from maternal transfer.

## Dosis

- **Skape en lammers ouer as 2 weke**  
Twee inspuitings van 1 ml elk, met 'n tussenpose van 6 weke en 'n jaarlikse skraag dosis.

Die entingskursus behoort ten minste 2 weke voor maksimum immuniteit verlang word voltooi te wees d.w.s óf 'n risikoperiode óf in dragtige ooie gedurende lamming.

Ooie wat reeds gesensitiseer is behoort 2 – 6 weke voor lamming geënt te word. Dit sal passiewe beskerming oordra via die biesmelk en lammers sal beskerm wees vir tot 12 weke.

Lammers van 2 weke oud kan geënt word, ongeag die serumvlak van maternale antitoksiene oorgedra

### **Koeie en kalwers ouer as 2 weke**

Twee inspuitings van 2 ml elk, met 'n tussenpose van 6 weke en 'n jaarlikse skraag dosis.

Koeie wat reeds gesensitiseer is behoort 2 – 6 weke voor kalwing geënt te word. Dit sal passiewe beskerming oordra via die biesmelk en kalwers sal beskerm wees vir tot 12 weke.

Kalwers van 2 weke oud kan ingeënt word, ongeag die serumvlak van maternale antitoksiene oorgedra.

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