

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribovax 10 suspension for injection for cattle and sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Active substances:

<i>C. perfringens</i> type A (α) toxoid	≥ 0.5 IU [#]
<i>C. perfringens</i> type B & C (β) toxoid	≥ 18.2 IU*
<i>C. perfringens</i> type D (ϵ) toxoid	≥ 5.3 IU*
<i>C. chauvoei</i> whole culture, inactivated	$\geq 90\%$ protection**
<i>C. novyi</i> toxoid	≥ 3.8 IU*
<i>C. septicum</i> toxoid	≥ 4.6 IU*
<i>C. tetani</i> toxoid	≥ 4.9 IU*
<i>C. sordellii</i> toxoid	≥ 4.4 U ¹
<i>C. haemolyticum</i> toxoid	≥ 17.4 U [#]

* ELISA According to Ph.Eur.

¹ In house ELISA

** Guinea pig challenge test according to Ph.Eur.

[#] *In vitro* toxin neutralisation test based on haemolysis of sheep erythrocytes.

Adjuvant:

Aluminium¹ 3.026 – 4.094 mg

¹ from aluminium potassium sulphate (alum)

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Thiomersal	0.05 – 0.18 mg
Sodium chloride	
Formaldehyde	
Water for injections	

Light brown aqueous suspension that settles on storage.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each target species

For the active immunisation of sheep and cattle against disease associated with infections caused by *Clostridium perfringens* type A, *C. perfringens* type B, *C. perfringens* type C, *C. perfringens* type D, *Clostridium chauvoei*, *Clostridium novyi* type B, *Clostridium septicum*, *Clostridium sordellii* and *Clostridium haemolyticum* and against tetanus caused by *Clostridium tetani*.

For the passive immunisation of lambs and calves against infections caused by the above mentioned clostridial species (except *C. haemolyticum* in sheep).

Onset of immunity:

Sheep and Cattle: 2 weeks after the basic vaccination course (as demonstrated by serology only).

Duration of active immunity:

As demonstrated by serology only:

Sheep: 1 year against *C. perfringens* type A, B, C and D, *C. novyi* type B, *C. sordellii*, *C. Tetani*;
< 6 months against *C. septicum*, *C. haemolyticum*, *C. chauvoei*;

Cattle: 1 year against *C. tetani* and *C. perfringens* type D;
< 1 year against *C. perfringens* type A, B and C;
< 6 months against *C. novyi* type B, *C. septicum*, *C. sordellii*, *C. haemolyticum*, *C. chauvoei*.

An anamnestic humoral immune response (immunological memory) to all components was demonstrated 1 year following the basic course of vaccination.

Duration of passive immunity:

As demonstrated by serology only:

Lambs: At least 2 weeks for *C. septicum* and *C. chauvoei*;
At least 8 weeks for *C. perfringens* type B and *C. perfringens* type C;
At least 12 weeks for *C. perfringens* type A, *C. perfringens* type D, *C. novyi* type B, *C. tetani* and *C. sordellii*;
No passive immunity was observed for *C. haemolyticum*.

Calves: At least 2 weeks for *C. sordellii* and *C. haemolyticum*;
At least 8 weeks for *C. septicum* and *C. chauvoei*;
At least 12 weeks for *C. perfringens* type A, *C. perfringens* type B, *C. perfringens* type C, *C. perfringens* type D, *C. novyi* type B, and *C. tetani*.

3.3 Contraindications

Do not use in sick or immunodeficient animals.

3.4 Special warnings

Vaccinate healthy animals only.

The effectiveness of the vaccine in providing passive immunity to young lambs and calves depends on these animals ingesting adequate amounts of colostrum on the first day of life.

Clinical trials have demonstrated that the presence of maternal derived antibodies (MDA), particularly against *C. tetani*, *C. novyi* type B, *C. perfringens* type A (calves only), *C. chauvoei* (lambs only) and *C. perfringens* type D may reduce the antibody response to vaccination in young lambs and calves. Therefore, to ensure an optimal response in young animals with high levels of MDA, the basic vaccination should be delayed until the levels wane (which is after about 8-12 weeks of age, see section 3.2).

3.5 Special precautions for use

Special precautions for safe use in the target species:

It is good practice to observe animals regularly for adverse reactions at the injection site following vaccination. It is recommended to seek medical advice from a veterinarian in case of a severe injection site reaction.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle and sheep:

Very common (>1 animal / 10 animals treated):	Injection site swelling ¹ .
Common (1 to 10 animals / 100 animals treated):	Injection site abscess, injection site skin discolouration ² . Hyperthermia ³ .
Uncommon (1 to 10 animals / 1,000 animals treated):	Injection site pain ⁴ .
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic type reaction ⁵ .

¹ Up to a mean value of 6 cm in sheep and 15 cm diameter in cattle; sometimes reactions of up to 25 cm diameter may be seen in cattle. Most local reactions resolve within 3-6 weeks in sheep and in less than 10 weeks in cattle. In a minority of animals they may persist longer.

² Returns to normal as the local reaction resolves.

³ Mild.

⁴ For 1-2 days post first vaccination.

⁵ In such cases appropriate treatment such as adrenaline should be administered without delay.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

No side effects other than those described under section 3.6 were seen when the vaccine was used in sheep and cattle between 8 and 2 weeks prior to parturition. In the absence of specific data, the use of the vaccine is not recommended during the first or second third of pregnancy.

Avoid stress in pregnant ewes and cows.

3.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

3.9 Administration routes and dosage

Subcutaneous use.

Dose:

- Sheep: 1 ml – from 2 weeks of age

- Cattle: 2 ml – from 2 weeks of age

Administration:

By subcutaneous injection preferably in the loose skin on the side of the neck, observing aseptic precautions.

Shake the bottle thoroughly before use.

Syringes and needles should be sterile before use and the injection should be made through an area of clean, dry skin taking precautions against contamination.

Basic vaccination: Two doses should be administered, 4-6 weeks apart (see section 3.2 and 3.4).

Re-vaccination: A single dose should be administered at 6 to 12 month intervals after the basic vaccination (see section 3.2.)

Use in pregnancy:

To provide passive protection of the offspring, via the colostrum, a single re-vaccination should be administered between 8 and 2 weeks before parturition, provided that animals have received a full basic vaccination course before pregnancy.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In calves and lambs, local reactions may increase slightly if twice the recommended dose is administered (see section 3.6).

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AB01, QI04AB01.

Inactivated clostridium vaccine. To stimulate active immunity in sheep and cattle against *C. chauvoei* and the toxins of *Clostridium perfringens* type A, *C. perfringens* type B, *C. perfringens* type C, *C. perfringens* type D, *C. novyi*, *C. septicum*, *C. tetani*, *C. sordellii*, and *C. haemolyticum* contained in the vaccine.

To provide passive immunity via the colostrum against the above mentioned clostridial infections in young lambs and calves.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.

Shelf life after first opening the immediate packaging: 8 hours.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C). Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Flexible low density polyethylene (LDPE) bottle with 50 ml or 100 ml, closed with a bromobutyl rubber stopper and held in place with an aluminium cap.

Pack sizes:

Cardboard box with one bottle of 50 ml (50 doses of 1 ml or 25 doses of 2 ml).

Cardboard box with one bottle of 100 ml (100 doses of 1 ml or 50 doses of 2 ml).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/286/001

8. DATE OF FIRST AUTHORISATION

10 September 2021

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

22 November 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).