1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribovax T suspension for injection for cattle.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of vaccine contains:

Active substances:

C. chauvoei whole culture	≥ 90% protection[**]
C. haemolyticum	≥ 10 U[#]
C. novyi type B toxoid	≥ 3.5 IU[*]
C. septicum toxoid	≥ 2.5 IU[*]
C. tetani toxoid	≥ 2.5 IU[*]

[**] Guinea pig challenge test according to Ph. Eur.
[#] *In vitro* toxin neutralisation test based on haemolysis of sheep erythrocytes.
[*] International Units of antitoxin, according to Ph. Eur.

Adjuvants:

Aluminium[1]	1 200 – 1 600 ppm

[1] from potassium aluminium sulphate

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.06 – 0.18 mg
Sodium chloride	
Water for injections / purified water	

Light brown aqueous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle from 2 weeks of age.

3.2 Indications for use for each target species

Active immunisation of cattle to reduce clostridial diseases caused by:
C. chauvoei, *C. septicum*, *C. novyi* type B, *C. haemolyticum* and *C. tetani*.

Onset of immunity: 2 weeks after the primary vaccination course.
Duration of active immunity: 1 year following the primary vaccination course, based on serological data.

Passive immunity of calves via colostrum of their vaccinated mothers to reduce clostridial diseases caused by the specified organisms.

Duration of passive immunity: 12 weeks for *C. tetani* and *C. novyi* type B; 8 weeks for *C. septicum* and *C. chauvoei* and 2 weeks for *C. haemolyticum*.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

The effectiveness of the vaccine in providing passive immunity to young calves depends on these animals ingesting adequate amounts of colostrum on the first day of life.
In any animal population, there may be a number of individuals which fail to respond fully to vaccination. Successful vaccination depends upon the correct storage and administration of the vaccine together with the animal's ability to respond. This can be influenced by such factors as genetic constitution, intercurrent infection, age, the presence of maternally derived antibodies, nutritional status, concurrent drug therapy and stress.

Stress in pregnant cows should be avoided.

3.5 Special precautions for use

Special precautions for safe use in the target species:
In the event of an anaphylactic reaction appropriate treatment such as adrenaline should be administered without delay.

Reduced efficacy against *C. septicum* and *C. chauvoei* may occur in calves vaccinated at 2 weeks of age.

Calves from vaccinated dams, immunised between 2 – 10 weeks of age, may have reduced protection against *C. tetani* and *C. novyi* type B due to the presence of maternally derived antibodies.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1], Injection site induration, Injection site reaction[2]
Common (1 to 10 animals / 100 animals treated):	Injection site abscess
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Injection site skin discolouration[3], Injection site pain[4]

[1] May reach 14 cm diameter. Most local reactions resolve in less than 10 weeks.
[2] Reactions in the underlying tissues at the injection site.
[3] Returns to normal as the local reaction resolves.

[4] For 1-2 days post first vaccination.

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 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 and lactation:
Can be used during pregnancy.
Do not use during lactation.

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:
Primary vaccination: 2 ml initial dose followed by a further 2 ml dose six weeks later.
In areas of high risk of infection from *C. haemolyticum*, an initial vaccination regime of two doses of 4 ml is recommended.

Revaccination: 2 – 4 ml, depending on severity of risk of infection from *C. haemolyticum*, at a 12-month interval.

Administration:
By subcutaneous injection preferably in the loose skin on the side of the neck, observing aseptic precautions.
Shake well before use. Syringes and needles should be sterilized before use and the injection should be made through an area of clean, dry skin, taking aseptic precautions against contamination.

Vaccination programme:
Cattle: The primary course of immunisation consists of a 2 ml initial dose followed by a further 2 ml dose six weeks later. In areas of high risk of infection from *C. haemolyticum* infection an initial vaccination regime of two doses of 4 ml is recommended. Revaccination is recommended using 2 – 4 ml, depending on severity of risk of infection from *C. haemolyticum*, at intervals of not less than one year.

Use during pregnancy: For passive protection of calves, previously vaccinated pregnant cattle should be vaccinated during the period 2 – 8 weeks before calving.

Calves: For an optimum immune response, calves from cows vaccinated during pregnancy should not be vaccinated until 8 – 12 weeks of age.

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

In calves, local reactions may increase slightly if twice the recommended dose is administered.

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

To stimulate active immunity in cattle against *C. chauvoei*, *C. novyi* type B, *C. haemolyticum* and the toxins of *C. septicum* and *C. tetani* contained in the vaccine.

To provide passive immunity via the colostrum against the above clostridial infections in 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: 3 years.
Shelf life after first opening the immediate packaging: 8 hours.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Cardboard box containing 1 flexible low density polyethylene bottle of 20 ml or 50 ml closed with a halogenobutyl rubber stopper and sealed with an aluminium cap.

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 Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/260/001

8. DATE OF FIRST AUTHORISATION

14/01/2005

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

15/08/2025

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).