Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribovax 10 suspension for injection for cattle and sheep

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of vaccine contains:

Active substances

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

Aluminium[1] 3.026 – 4.094 mg
[1] from aluminium potassium sulphate (alum)

Excipient

Thiomersal 0.05 – 0.18mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection
Light brown aqueous suspension that settles on storage.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and sheep.

4.2 Indications for use, specifying the 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: Two weeks after the basic vaccination course (as demonstrated by serology only).

Duration of active immunity:
As demonstrated by serology only:

Sheep:	12 months 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:	12 months against *C. tetani* and *C. perfringens* type D < 12 months 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 12 months 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*

4.3 Contraindications

Do not use in sick or immunodeficient animals.

4.4 Special warnings for each target species

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 4.2).

4.5 Special precautions for use

Special precautions for use in animals
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.

4.6 Adverse reactions (frequency and seriousness)

Swelling at the injection site was observed very commonly in clinical studies. This may reach 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.
An abscess may develop commonly.
Skin discolouration at the injection site (which returns to normal as the local reaction resolves) may occur commonly.
Mild hyperthermia may occur commonly.

Localised pain at the injection site for 1-2 days post first vaccination may occur uncommonly.

Anaphylactic reactions were observed in very rare cases in spontaneous pharmacovigilance reports. In such cases appropriate treatment such as adrenaline should be administered without delay.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Pregnancy:
No side effects other than those described under section 4.6 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.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

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 4.2 and 4.4).
Re-vaccination: A single dose should be administered at 6 to 12 month intervals after the basic vaccination (see section 4.2.)

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In calves and lambs, local reactions may increase slightly if twice the recommended dose is administered (see section 4.6).

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Bovidae and Ovidae, inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia) for cattle and sheep, clostridium.

ATC-vet 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium potassium sulphate (alum)
Thiomersal
Sodium chloride
Water for injections
Formaldehyde

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 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.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Flexible low density polyethylene (LDPE) bottle with 20 ml, 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 20 ml (20 doses of 1 ml or 10 doses of 2 ml).
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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/286/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 September 2021

10 DATE OF REVISION OF THE TEXT

January 2022