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 dose of vaccine contains:

Active substances	Potency value/mL
C. perfringens type A (α) toxoid	≥ 0.5 U[#]
C. perfringens type B & C (β) toxoid	≥ 18.2 IU*
C. perfringens type D (ε) toxoid	≥ 5.3 IU*
*C. chauvoei*whole culture	≥ 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[#]
Adjuvant	
Aluminium potassium sulphate (alum)	3,026 – 4,094 ppm
Excipients	
Thiomersal	0.05-0.18mg
Formaldehyde	≤ 0.5 mg/ml

* 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.

For a 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

Sheep and cattle.

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:
Two weeks after the primary vaccination course.

Duration of active immunity:
An anamnestic humoral immune response (immunological memory) to all components was demonstrated 12 months following the primary course of vaccination.

As demonstrated by serology/persistent antibody titre 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*

Duration of passive immunity:
As demonstrated by serology/persistent antibody titre only:

For 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*.
For 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 vaccinate sick or immunodeficient animals.

4.4 Special warnings for each target species

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 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 primary 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
In the event of an anaphylactic reaction appropriate treatment such as adrenaline should be administered without delay.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In the case of accidental self-injection, encourage bleeding and wash the area immediately with water.If a local reaction develops, seek medical advice showing the package insert or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

75 - 100% of animals vaccinated with Tribovax10 may experience reactions to vaccination.

Most commonly reported adverse reactions are localised swelling or induration at the injection site but may also include mildhyperthermia, abscess or other reaction in the underlying tissues at the injectionsite.

Swelling at the injection site occurs in the majority of animals. This may reach up to a mean value of 6 cm in sheep and 15 cm diameter in cattle; occasionally 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, but may persist longer in a minority of animals.

An abscess may develop in some animals.

Vaccination may give rise to reactions in the underlying tissues at the injection site.

Skin discolouration at the injection site (which returns to normal as the local reaction resolved) may occur.

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

The local reactions do not affect the general health, demeanour, feeding or weight gain of the animals.

4.7 Use during pregnancy, lactation or lay

No side effects other than those described under 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.

Avoid stress in pregnant ewes and cows.

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

Sheep – from 2 weeks of age
Dose - 1 ml

Cattle – from 2 weeks of age
Dose – 2 ml

Administration: By subcutaneous injection at a suitable site.The recommended site is the loose skin on the side of the neck.

Shake well 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.

Primary vaccination: Two doses should be administered, 4-6 weeks apart.

Booster vaccination: A single dose should be administered at 6 to 12 month intervals .

Use in pregnancy
To provide passive protection of the offspring, via the colostrum, a single booster dose should be administered between 8 and 2 weeks before parturition, provided that animals have received a full primary 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 (refer to section 4.6).

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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 clostridial infections in young lambs and calves

ATCvet code: QI02AB01

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium potassium sulphate (alum)
Thiomersal
Formaldehyde
Sodium Chloride (0.85% solution)

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).
Protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

Cardboard box with 1 flexible low density polyethylene bottle of 20, 50 or 100 ml with a pharmaceutical grade halogenobutyl rubber bung held in place with an aluminium seal.
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)

VPA10996/259/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of fist authorisation: 19 December 2008
Date of last renewal: 13 June 2014

10 DATE OF REVISION OF THE TEXT