Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribovax T

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance(s):	**Potency Value per ml:**
C. chauvoei whole culture	Ph.Eur.
C. haemolyticum	≥ 10 U
C. novyi type B toxoid	≥ 3.5 IU
C. septicum toxoid	≥ 2.5 IU
C. tetani toxoid	≥ 2.5 IU

Adjuvant:

Potassium aluminium sulphate

Preservative:

Thiomersal

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle from 2 weeks of age

4.2 Indications for use, specifying the 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*.

The onset of immunity is two weeks after the primary course. Although direct challenge studies have not been performed the duration of immunity, based on serological data, is 1 year.

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

The duration of passive immunity varies from 12 weeks for *C. tetani* and *C. novyi type B*; to 8 weeks for *C. septicum* and *C. chauvoei* and 2 weeks for *C. haemolyticum*.

4.3 Contraindications

None

4.4 Special warnings for each target species

The effectiveness of the vaccine in providing passive immunity to young calves depends on these animals ingesting adequate amounts of colostrums 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.

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.

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* a *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

None.

4.6 Adverse reactions (frequency and seriousness)

75 - 100% of vaccinated animals may experience reactions to vaccination. These reactions are usually localised swelling or induration at the injection site but may also include abscess or other reaction in the underlying tissues at the injection site.
Swelling at the injection site occurs in the majority of animals and may reach 14 cm diameter. Most local reactions resolve in less then 10 weeks. In up to 17% of animals an abscess may develop. Vaccination may give rise to reactions in the underlying tissues at the injection site.
Skin discolouration (which returns to normal as the local reaction resolved) and localised pain for 1-2 days post first vaccination may occur at the injection site.

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amounts to be administered and administration route

Dose:
Primary vaccination:
2 ml initial dose followed by a further 2 ml dose six week's 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:
2 – 4 ml, depending on severity of risk 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 thoroughly 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 immunization consists of a 2 ml initial dose followed by a further 2 ml dose six week's 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.

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

In calves, 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

Pharmacotherapeutic group: Immunologicals, immunologicals for bovidae, cattle, inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia), clostridium.

ATC vet 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium aluminium sulphate
Thiomersal
Sodium chloride

6.2 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: 3 years
Shelf-life after first opening the immediate packaging: 8 hours

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive,
Magna Business Park,
Citywest Road,
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/260/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13th January 2010

10 DATE OF REVISION OF THE TEXT

April 2012