SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribovax T

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient	**per ml**
Active ingredients	
C. haemolyticum	≥ 17.4 U
C. chauvoei whole culture	meets Ph Eur.
C. novyi type B toxoid	≥ 5.5 IU
C. septicum toxoid	≥ 4.6 IU
C. tetani toxoid	≥ 3.5 IU
Excipients	
Potash alum (adjuvant)	2.5% w/v
Thiomersal (preservative)	0.015% w/v

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

For the active immunisation of cattle against diseases associated with infections caused by *Clostridium chauvoei*, *Clostridium novyi* type B, *Clostridium septicum*, and *Clostridium haemolyticum* and against tetanus caused by *Clostridium tetani*.

Onset of immunity: two weeks after the primary 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:

12 months against *C. tetani*
<6 months against *C. novyi* type B, *C. septicum, C. haemolyticum, C.chauvoei*

4.3 Contraindications

None.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals

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, immunized 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

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 leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Most vaccinated animals may experience reactions to vaccination. These reactions are usually localised swelling or induration at the injection site but may also include mild hyperthermia, abscess or other reaction in the underlying tissues at the injection site.

Swelling at the injection site occurs in the majority of animals. This may reach up to 14 cm diameter in cattle. 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

No side effects other than those described under 4.6 are expected when the vaccine is used in cattle between 8 and 2 weeks prior to parturition. In the absence of specific data, no recommendation can be made for use of the vaccine during the first or second trimester of pregnancy.

Avoid stress in pregnant cows.

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 except those mentioned above.

A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be decided on a case by case basis.

4.9 Amounts to be administered and administration route

Dose:

Primary vaccination:

Cattle of all ages: 4 ml initial dose followed by a second 4 ml dose 6 weeks later.

Revaccination:

A single dose (4 ml) should be administered at 12 month intervals.

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.

The vaccine course should be completed at least two weeks before maximum immunity is required. This may be either a period of risk or in pregnant cattle 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.

4.11 Withdrawal period(s)

Zero days

5. IMMUNOLOGICAL PROPERTIES

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.
ATCvet code: QI02AB01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potash alum
Thiomersal
Formaldehyde
Sodium chloride solution

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 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 bottle of 100 ml, 250 ml or 500 ml flexible bottles constructed of low density polyethylene and closed with a pharmaceutical grade 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 product or waste materials derived from the use of such products, if appropriate.

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 UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4554

9. DATE OF FIRST AUTHORISATION

19 October 2005

10. DATE OF REVISION OF THE TEXT

September 2015

Approved: 03 September 2015