PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribovax T

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:

C. haemolyticum	≥ 7.4 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
Thiomersal	0.015 % w/v
Potash alum	2.5% w/v

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100 ml

250 ml

500 ml

Dose: 4 ml.

5. TARGET SPECIES

Target species: Cattle.

6. INDICATION(S)

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*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Route: subcutaneous injection.

Read package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Shake thoroughly before use.

10. EXPIRY DATE

Expiry date

Shelf life after first opening of the container: 8 hours

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2 °C – 8 °C).

Protect from light.

Do not freeze.

Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-VPS

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA holder:

Intervet UK Ltd.
Walton Manor
Walton
Milton Keynes
Bucks. MK7 7AJ

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4554

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribovax T

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains: ≥ 17.4 U *C. haemolyticum*, whole culture that meets Ph.Eur. of *C. chauvoei*, ≥ 5.5 IU *C. novyi* type B toxoid, ≥ 4.6 IU *C. septicum* toxoid, ≥ 3.5 IU *C. tetani toxoid*, 0.015% Thiomersal and 2.5% Potash alum.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100 ml

250 ml

500 ml

Dose: 4 ml

5. TARGET SPECIES

Target species: Cattle.

6. INDICATION(S)

Not applicable.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Route: SC injection.

Read package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

10. EXPIRY DATE

Expiry date:

Shelf life after first opening of the container: 8 hours.

11. SPECIAL STORAGE CONDITIONS

Read package leaflet before use.

Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-VPS

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Read package leaflet before use.

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4554

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR:

Tribovax T

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder

Intervet UK Ltd.

Walton Manor

Walton

Milton Keynes

Bucks MK7 7AJ

Manufacturer for the batch release[1]:

Intervet UK Ltd.

Walton Manor, Walton,

Milton Keynes

Buckinghamshire, MK7 7AJ

United Kingdom

Intervet International B.V.

Wim de Körverstraat 35

5831 AN Boxmeer

The Netherlands

[1] The printed package leaflet will state the name and address of the manufacturer responsible for the release of the concerned batch only.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribovax T

Suspension for injection.

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Active ingredient	**per ml**
Clostridium haemolyticum	≥ 17.4 U
Clostridium chauvoei whole culture	meets Ph. Eur.
Clostridium novyi type B toxoid	≥ 5.5 IU
Clostridium septicum toxoid	≥ 4.6 IU

Clostridium tetani toxoid	≥ 3.5 IU

Excipients

Potash alum (adjuvant)	2.5 % w/v
Thiomersal (preservative)	0.015 % w/v

4. INDICATION(S)

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:

Anamnestic humoral immune response (immunological memory) to all components 12 months following the primary course of vaccination.

Serology/persistent antibody titre only:	12 months against *C. tetani*
	<6 months against *C. novyi* type B, *C. septicum*, *C. haemolyticum*, *C.chauvoei.*

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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 than 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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (from 2 weeks of age).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dose: 4 ml.

Administration: By subcutaneous injection preferably in the loose skin on the side of the neck, observing aseptic precautions.

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport in a refrigerator (2 °C to 8 °C).

Protect from light.

Do not freeze.

Keep the container in the outer carton.

Do not use after the expiry date stated on the label and carton.

Shelf-life after first opening the container: 8 hours.

12. SPECIAL WARNING(S)

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.

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 label to the physician.

Use during pregnancy

No side effects other than those described in section “Adverse reactions” 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.

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.

Incompatibilities

Do not mix with any other veterinary medicinal products.

Overdose:

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2018.

15. OTHER INFORMATION

For animal treatment only.

Pack sizes:

100 ml, 250 ml or 500 ml.

Not all pack sizes may be marketed.

MA number: Vm 01708/4554

Legal category:

POM-VPS

To be supplied only on veterinary prescription.

Approved: 11 January 2019