PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle Label – 50 ml/ 100 ml

1. NAME OF THE MEDICINAL PRODUCT

Bravoxin 10, suspension for s.c. injection for cattle and sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1 ml dose contains:

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
C. haemolyticum toxoid	≥ 17.4 U

Aluminium potassium sulphate (alum), formaldehyde, thiomersal.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

Cattle and sheep

6. INDICATION(S)

Vaccine against clostridial infections.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

s.c. injection
Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous – read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year} Once broached use within 8 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Protect from light.
Do not freeze.

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

Not applicable – no text will be included

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

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

Not applicable – no text will be included

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4585

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIUMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bravoxin 10 *[pictogram maybe used]*

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Read the package leaflet before use.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml

4. ROUTE(S) OF ADMINISTRATION

s.c. injection

5. WITHDRAWAL PERIOD

Withdrawal period: zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE MEDICINAL PRODUCT

Bravoxin 10, suspension for injection for cattle and sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1 ml dose contains:

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
C. haemolyticum toxoid	≥ 17.4 U

Aluminium potassium sulphate (alum), formaldehyde, thiomersal.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

20 ml
50 ml
100 ml

5. TARGET SPECIES

Cattle and sheep from 2 weeks of age.

6. INDICATION(S)

Vaccine against clostridial infections.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous injection.
Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous – read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 8 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Protect from light.
Do not freeze.

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

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

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

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4585

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PACKAGE LEAFLET FOR:
Bravoxin 10
Suspension for injection for cattle and sheep

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

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release[1]:
MSD Animal Health 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.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bravoxin 10, suspension for injection for cattle and sheep

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

Light brown aqueous suspension that settles on storage.

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

Each 1 ml dose of vaccine contains:

Active Ingredient	**Potency per 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#

* 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 potassium sulphate (alum)	3,026 – 4,094 ppm

Excipient

Thiomersal	0.05 – 0.18mg
Formaldehyde	≤ 0.5 mg/ml

4. INDICATION(S)

For the active immunisation of sheep and cattle against diseases caused by *Clostridium perfringens* type A, *C. perfringens* type B, *C. perfringens* type C, *C. perfringens* type D, *C. chauvoei*, *C. novyi* type B, *C. septicum*, *C. sordellii*, *C. haemolyticum* and against tetanus caused by *C. tetani*. For the passive immunisation of lambs and calves against infection 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* and *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 is:

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 and at least twelve 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* and at least twelve 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*.

5. CONTRAINDICATIONS

Do not vaccinate sick or immunodeficient animals.

6. ADVERSE REACTIONS

75%–100% of animals vaccinated with Bravoxin 10 may experience reactions to vaccination.

Most commonly reported reactions are 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 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.

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

7. TARGET SPECIES

Sheep and cattle

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

Sheep – from 2 weeks of age
Dose – 1 ml

Cattle – from 2 weeks of age
Dose – 2 ml

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label and the carton.

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

12. SPECIAL WARNING(S)

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).

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.

Pregnancy:
No side effects other than those already described 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, no recommendation can be made for use of the vaccine during the first or second third of pregnancy. Avoid stress in pregnant ewes and cows.

Overdose (symptoms, emergency procedures, antidotes):
In calves and lambs, local reactions may increase slightly if twice the recommended dose is administered.

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.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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

October 2020

15. OTHER INFORMATION

Packs containing 1 bottle of 20 ml, 50 ml or 100 ml.
Not all pack sizes may be marketed.