

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box for 50 ml and 100 ml bottles

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Covexin 10 Suspension for injection for sheep and cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 ml of vaccine contains:

<i>C. perfringens</i> type A toxoid	≥ 0.9 U
<i>C. perfringens</i> type B & C (β) toxoid	≥ 12.4 U
<i>C. perfringens</i> type D (ε) toxoid	≥ 5.1 U
<i>C. chauvoei</i> whole culture, inactivated	meets Ph. Eur.
<i>C. novyi</i> toxoid	≥ 1.2 U
<i>C. septicum</i> toxoid	≥ 3.6 U
<i>C. tetani</i> toxoid	≥ 2.5 U
<i>C. sordellii</i> toxoid	≥ 0.8 U
<i>C. haemolyticum</i> toxoid	≥ 16.5 U

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

For sheep and cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dose:

Sheep – 2 × 1 ml, 4-6 weeks apart.

Cattle – 2 × 2 ml, 4-6 weeks apart.

Shake thoroughly before use. For subcutaneous injection. The recommended site is the loose skin on the side of the neck.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

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

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

Dispose of waste material in accordance with national requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/3020

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Covexin 10 Suspension for injection for sheep and cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 ml of vaccine contains:

<i>C. perfringens</i> type A toxoid	≥ 0.9 U
<i>C. perfringens</i> type B & C (β) toxoid	≥ 12.4 U
<i>C. perfringens</i> type D (ε) toxoid	≥ 5.1 U
<i>C. chauvoei</i> whole culture, inactivated	meets Ph. Eur.
<i>C. novyi</i> toxoid	≥ 1.2 U
<i>C. septicum</i> toxoid	≥ 3.6 U
<i>C. tetani</i> toxoid	≥ 2.5 U
<i>C. sordellii</i> toxoid	≥ 0.8 U
<i>C. haemolyticum</i> toxoid	≥ 16.5 U

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

For sheep and cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

SC.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

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

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/3020

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Covexin 10 Suspension for injection for sheep and cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 1 ml of vaccine contains:

<i>C. perfringens</i> type A toxoid	≥ 0.9 U
<i>C. perfringens</i> type B & C (β) toxoid	≥ 12.4 U
<i>C. perfringens</i> type D (ε) toxoid	≥ 5.1 U
<i>C. chauvoei</i> whole culture, inactivated	meets Ph. Eur.
<i>C. novyi</i> toxoid	≥ 1.2 U
<i>C. septicum</i> toxoid	≥ 3.6 U
<i>C. tetani</i> toxoid	≥ 2.5 U
<i>C. sordellii</i> toxoid	≥ 0.8 U
<i>C. haemolyticum</i> toxoid	≥ 16.5 U

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

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

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Covexin 10 Suspension for injection for sheep and cattle

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

Marketing authorisation holder:

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-La-Neuve
BELGIUM

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Covexin 10 Suspension for injection for sheep and cattle

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

Each 1 ml of vaccine contains:

Active substances

<i>C. perfringens</i> type A toxoid	≥ 0.9 U
<i>C. perfringens</i> type B & C (β) toxoid	≥ 12.4 U
<i>C. perfringens</i> type D (ε) toxoid	≥ 5.1 U
<i>C. chauvoei</i> whole culture, inactivated	meets Ph. Eur.
<i>C. novyi</i> toxoid	≥ 1.2 U
<i>C. septicum</i> toxoid	≥ 3.6 U
<i>C. tetani</i> toxoid	≥ 2.5 U
<i>C. sordellii</i> toxoid	≥ 0.8 U
<i>C. haemolyticum</i> toxoid	≥ 16.5 U

Adjuvant:

Alum 3.03 – 4.09 mg Aluminium

Excipient:

thiomersal

0.05 – 0.18 mg

Suspension for injection.

Light brown aqueous suspension that settles on storage.

4. INDICATION(S)

For the active immunisation of sheep and cattle against diseases 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: 2 weeks after the basic vaccination course (as demonstrated by serology only).

Duration of active immunity as demonstrated by serology 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*

Additionally, an anamnestic humoral immune response (immunological memory) to all components was demonstrated after antigen stimulation 12 months after the basic vaccination course.

Duration of passive immunity as demonstrated by serology only:

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 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*.

Calves:

At least 2 weeks for *C. sordellii*, and *C. haemolyticum*, at least 8 weeks for *C. septicum* and *C. chauvoei* and 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*.

5. CONTRAINDICATIONS

Do not use in sick or immunodeficient animals.

6. ADVERSE REACTIONS

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

Very commonly, animals vaccinated with Covexin 10 may experience reactions to vaccination. These reactions are usually localised swelling, induration or other reaction in the underlying tissue at the injection site (very commonly) but may also include mild hyperthermia (very commonly). Swelling at the injection site occurs very commonly. This swelling may reach up to a mean value of 6 cm in diameter in sheep and 15 cm in diameter in cattle; though some cattle reactions of up to 25 cm in diameter may be observed. Most local reactions resolve within 3-6 weeks in sheep and in less than 10 weeks in cattle but may persist longer. Commonly, an abscess may develop in some animals.

Skin discolouration at the injection site (which returns to normal as the local reaction resolves) may commonly occur. Localised pain at the injection site for 1-2 days post first vaccination may occur commonly.

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

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively, you can report via your national reporting system {national system details}.

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.

Administration:

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

The bottle should be well shaken before any vaccine is withdrawn. 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.

Basic vaccination scheme:

Two doses should be administered, 4-6 weeks apart (refer to section 'Indications' and section 'Special warning(s)').

Re-vaccination scheme:

A single dose should be administered every 6 to 12 months after the basic vaccination scheme (see also section 'Indications').

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 basic vaccination course before pregnancy.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

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 carton after EXP.

Shelf life after first opening the immediate packaging: 8 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only.

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, 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 basic vaccination should be delayed until the levels wane (which is after about 8-12 weeks of age, see section 'Indications').

Special precautions for use in animals:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy:

No side effects other than those described under Adverse Reactions 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.

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.

Overdose (symptoms, emergency procedures, antidotes):

In calves and lambs, local reactions may increase slightly if twice the recommended dose is administered (refer to section 'Adverse Reactions').

Incompatibilities:

Do not mix with any other veterinary medicinal product.

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

Medicines should not be disposed of via wastewater or household waste. Dispose of waste material in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2020

15. OTHER INFORMATION

Flexible high-density polyethylene (HDPE) bottle containing 50 ml or 100 ml. The plastic bottle is closed with a pharmaceutical grade chlorobutyl rubber stopper held in place with an aluminium cap.

Cardboard box with 1 bottle of 50 doses of 1 ml or 25 doses of 2 ml (50 ml).
Cardboard box with 1 bottle of 100 doses of 1 ml or 50 doses of 2 ml (100 ml).

Not all pack sizes may be marketed.

Approved: 29/01/21

A handwritten signature in black ink, appearing to read "D. Austin", with a horizontal line extending to the right from the end of the signature.