1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Covexin 8 suspension for injection for sheep and cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Active substances:	Potency value/Quantity/mL
C. *perfringens* type B & C (ß) toxoid	≥ 11.6 U*
C. *perfringens* type D (e) toxoid	≥ 7.1 U*
C. *chauvoei* whole culture	meets Ph. Eur.**
C. *novyi* type B anaculture	≥ 2.3 U*
C. *septicum* toxoid	≥ 3.2 U*
C. *tetani* toxoid	≥ 1.3 U*
C. *haemolyticum* anaculture	≥ 10 U#

* In house ELISA ** Challenge test according to Ph.Eur.
# In vitro toxin neutralisation test based on haemolysis of sheep erythrocytes.

Adjuvant

Alum	1.20 - 1.60 mg as aluminium

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Alum Thiomersal	0.12 - 0.18 mg
Sodium chloride	
Formaldehyde	= 0.5 mg

Light brown aqueous suspension that settles on storage.

3. CLINICAL INFORMATION

3.1 Target species

Sheep and cattle.

3.2 Indications for use for each target species

For the active immunisation of cattle and sheep to reduce clostridial diseases caused by:
Sheep:
C. perfringens type B, *C. perfringens* type C, *C. perfringens* type D, *C. septicum*, *C. novyi* type B, *C. chauvoei*, *C. haemolyticum*, and *C. tetani*.

Cattle:
Adults – *C. perfringens* type B, *C. perfringens* type C, *C. perfringens* type D, *C. septicum, C. chauvoei, C. novyi* type B, *C. haemolyticum* and *C. tetani.*
Calves - *C. perfringens* type B, *C. perfringens* type C, *C. novyi* type B and *C. tetani.*
Onset of immunity: 2 weeks after the primary course.
Duration of immunity: Although direct challenge studies have not been performed the duration of immunity, based on serological data, is 1 year.

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

Lambs:
The duration of passive immunity: varies from 8 to 12 weeks for *C. tetani, C. novyi* type B, *C. perfringens* type B and C and *C. perfringens* D and 2 weeks for *C. septicum* and *C. chauvoei*. Passive immunity against *C. haemolyticum* could not be demonstrated. Passive immunity has been claimed on the basis of antibody responses.
Calves:
The duration of passive immunity: varies from 12 weeks for *C. tetani, C. novyi* type B, *C. perfringens* type B and C and *C. perfringens* D; to 8 weeks for *C. septicum* and *C. chauvoei*. Passive immunity against *C. haemolyticum* was only evident in 2-week old animals.

3.3 Contraindications

None.

3.4 Special warnings

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.

Reduced efficacy against *C. perfringens* type D, *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, C. perfringens* types B, C and D and C. *novyi* type B due to the presence of maternally derived antibodies.

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Prior to first time use on a farm, it is strongly recommended that the advice of a veterinary surgeon is sought.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection encourage bleeding and wash the area immediately with water. If symptoms develop, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Sheep and cattle:

Very common (>1 animal / 10 animals treated):	Injection site abscess[1], Injection site induration[1], Injection site reaction[1], Injection site swelling[2], Injection site warmth[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain[3], Injection site skin discoloration[4], Anaphylactic-type reaction[5]

[1] Most local reactions resolve in 3-6 weeks in sheep and in less than 10 weeks in cattle.
[2] This can reach up to 6 cm in sheep and 14 cm in diameter in cattle.
[3] May occur for 1-2 days after the first vaccination.
[4] Returns to normal when the local reaction resolves.
[5] If such reaction occurs, appropriate treatment such as adrenaline should be administered without delay.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy
The vaccine has been shown to be safe and efficacious 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 trimester of pregnancy. Avoid stress in pregnant ewes and cows.

3.8 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.

3.9 Administration routes and dosage

Subcutaneous use.
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.

Dose:
Primary vaccination:
Sheep and lambs over 8 weeks of age: 5 ml initial dose followed by a 2 ml dose 6 weeks later.
Lambs 2-8 weeks of age, from unvaccinated ewes or ewes of unknown vaccination status: 2 ml initial dose followed by a second 2 ml dose 4-6 weeks later.
Cattle of all ages: 5 ml initial dose followed by a second 5 ml dose 6 weeks later.

Revaccination:
A single dose (2 ml for sheep, 5 ml for cattle) should be administered at 12 month intervals.

Vaccination Programme:
Sheep: 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 ewes during lambing.

Use during pregnancy: In lambing flocks, to ensure maximum protection of the lambs until 12 weeks of age, previously vaccinated ewes are best injected 2 weeks before lambing is due to commence. However, provided lambing in the group will not extend beyond a 6 week period, previously vaccinated pregnant ewes may be injected at any time from 6 to 2 weeks before the group is due to commence lambing.

Lambs: Lambs born from fully vaccinated ewes should not be given their first dose of the veterinary medicinal product until 8-12 weeks of age, since the presence of maternally derived antibodies may interfere with the response to *C. tetani* and *C. novyi type B*. Lambs born from unvaccinated ewes may be given their first dose of the veterinary medicinal from 2 weeks of age.

Cattle: 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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In calves, local reactions may increase slightly if twice the recommended dose is administered (refer to section 3.6).

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AB01, QI04AB01

To stimulate active immunity in sheep and cattle against *C. chauvoei, C. perfringens* type B, *C. novyi* type B, *C. haemolyticum* and the toxins of *C. perfringens* type C, *C. perfringens* type D, *C. Septicum* and *C. tetani* contained in the vaccine.

To provide passive immunity via the colostrum against the above mentioned clostridial infections in young lambs and calves.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product. .

5.2 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.

5.3 Special precautions for storage

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

Protect from light.

5.4 Nature and composition of immediate packaging

Cardboard box containing 1 high density polyethylene bottle of 100 ml or 250 ml sealed with a rubber stopper and closed with an aluminium cap.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

7. MARKETING AUTHORISATION NUMBER

VPA10387/009/001

8. DATE OF FIRST AUTHORISATION

11/07/2014

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

31/03/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX
100 ml
250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Covexin 8 suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active Ingredient	Potency value/ quantity/ml
C. perfringens type B & C (β) toxoid	≥ 11.6 U
C. perfringens type D (ε) toxoid	≥ 7.1 U
C. haemolyticum	≥ 10 U
C. chauvoei whole culture	meets Ph. Eur.
C. novyi type B toxoid	≥ 2.3 U
C. septicum toxoid	≥ 3.2 U
C. tetani toxoid	≥ 1.3 U

3. PACKAGE SIZE

100 ml
250ml

4. TARGET SPECIES

Sheep and cattle.

5. INDICATIONS

For the active immunisation of sheep and cattle to reduce clostridial diseases caused by C. *perfringens* type B, C. *perfringens* type C, C. *perfringens* type D, C. *septicum*, C. *novyi* type B, C. *chauvoei*, C. *haemolyticum*, and C. *tetani*.

For passive immunisation of lambs and calves via colostrum of their vaccinated mothers to reduce clostridial diseases caused by the specified organisms (except C. *haemolyticum* in sheep).

The onset of immunity is two weeks after the primary course and although direct challenge studies have not been performed the duration of immunity, and revaccination is required every 12 months.

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once openeduse within 8 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.

Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

14. MARKETING AUTHORISATION NUMBERS

VPA 10387/009/001

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL
100 ml
250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Covexin 8 suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active Ingredient	Potency value/Quantity/mL
C. perfringens type B & C (β) toxoid	≥ 11.6 U
C. perfringens type D (ε) toxoid	≥ 7.1 U
C. haemolyticum	≥ 10 U
C. chauvoei whole culture	meets Ph. Eur.
C. novyi type B toxoid	≥ 2.3 U
C. septicum toxoid	≥ 3.2 U
C. tetani toxoid	≥ 1.3 U

3. TARGET SPECIES

Sheep and cattle.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Subcutaneous use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 8 hours.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Covexin 8 suspension for injection for sheep and cattle

2. Composition

Each ml contains:

Active substances:

Active substances:	Potency value/Quantity/mL
C. *perfringens* type B & C (ß) toxoid	≥ 11.6 U*
C. *perfringens* type D (e) toxoid	≥ 7.1 U*
C. *chauvoei* whole culture	meets Ph. Eur.**
C. *novyi* type B anaculture	≥ 2.3 U*
C. *septicum* toxoid	≥ 3.2 U*
C. *tetani* toxoid	≥ 1.3 U*
C. *haemolyticum* anaculture	≥ 10 U#

* In house ELISA
** Challenge test according to Ph.Eur.
# In vitro toxin neutralisation test based on haemolysis of sheep erythrocytes.

Adjuvant

Alum	1.20 - 1.60 mg as aluminium

Excipients:

Alum Thiomersal	0.12 - 0.18 mg
Formaldehyde	= 0.5 mg

Light brown aqueous suspension that settles on storage.

3. Target species

Sheep and cattle.

4. Indications for use

For the active immunisation of cattle and sheep to reduce clostridial diseases caused by:
Sheep:
C. perfringens type B, *C. perfringens* type C, *C. perfringens* type D, *C. septicum*, *C. novyi* type B, *C. chauvoei*, *C. haemolyticum*, and *C. tetani*.

Cattle:
Adults – *C. perfringens* type B, *C. perfringens* type C, *C. perfringens* type D, *C. septicum*, *C. chauvoei*, *C. novyi* type B, *C. haemolyticum* and *C. tetani*.
Calves - *C. perfringens* type B, *C. perfringens* type C, *C. novyi* type B and *C. tetani*.

Onset of immunity: 2 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 and lambs via colostrum of their vaccinated mothers to reduce clostridial diseases caused by the specified organisms:

Lambs:
The duration of immunity: varies from 8 to 12 weeks for *C. tetani*, *C. novyi type B, C. perfringens* type B and C and *C. perfringens* D and 2 weeks for *C. septicum* and *C. chauvoei*. Passive immunity against *C. haemolyticum* could not be demonstrated. Passive immunity has been claimed on the basis of antibody responses.
Calves:
The duration of immunity: varies from 12 weeks for *C. tetani*, *C. novyi type B, C. perfringens* type B and C and *C. perfringens* D; to 8 weeks for *C. septicum* and *C. chauvoei*. Passive immunity against *C. haemolyticum* was only evident in 2-week old animals.

5. Contraindications

None.

6. Special warnings

Special warnings:

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.

Vaccinate healthy animals only.

Reduced efficacy against *C. perfringens* type D, *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, C. perfringens* types B, C and D and C. *novyi* type B due to the presence of maternally derived antibodies.

Special precautions for safe use in the target species:
Prior to first time use on a farm, it is strongly recommended that the advice of a veterinary surgeon is sought.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection encourage bleeding and wash the area immediately with water. If symptoms develop, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy:
The vaccine has been shown to be safe and efficacious 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 trimester 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:
In calves, local reactions may increase slightly if twice the recommended dose is administered (refer to section 'adverse events').

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Sheep and cattle:

Very common (>1 animal / 10 animals treated):	Injection site abscess[1], Injection site induration[1], Injection site reaction[1], Injection site swelling[2], Injection site warmth[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site pain[3], Injection site skin discoloration[4], Anaphylactic-type (severe allergic) reaction[5]

[1] Most local reactions resolve in 3-6 weeks in sheep and in less than 10 weeks in cattle.
[2] This can reach up to 6 cm in sheep and 14 cm in diameter in cattle.
[3] May occur for 1-2 days after the first vaccination.
[4] Returns to normal when the local reaction resolves.
[5] If such reaction occurs, appropriate treatment such as adrenaline should be administered without delay.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: www.hpra.ie

8. Dosage for each species, routes and method of administration

Dose:
Primary vaccination:
Sheep and lambs over 8 weeks of age: 5 ml initial dose followed by a 2 ml dose 6 weeks later.
Lambs 2-8 weeks of age, from unvaccinated ewes or ewes of unknown vaccination status: 2 ml initial dose followed by a second 2 ml dose 4-6 weeks later.
Cattle of all ages: 5 ml initial dose followed by a second 5 ml dose 6 weeks later.

Revaccination:
A single dose (2 ml for sheep, 5 ml for cattle) should be administered at 12 month intervals.

Vaccination Programme:
Sheep: 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 ewes during lambing.

Use during pregnancy: In lambing flocks, to ensure maximum protection of the lambs until 12 weeks of age, previously vaccinated ewes are best injected 2 weeks before lambing is due to commence. However, provided lambing in the group will not extend beyond a 6 week period, previously vaccinated pregnant ewes may be injected at any time from 6 to 2 weeks before the group is due to commence lambing.

Lambs: Lambs born from fully vaccinated ewes should not be given their first dose of the veterinary medicinal product until 8-12 weeks of age, since the presence of maternally derived antibodies may interfere with the response to *C. tetani* and *C. novyi* type B.
Lambs born from unvaccinated ewes may be given their first dose of the veterinary medical product from 2 weeks of age.

Cattle: 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.

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.

9. Advice on correct administration

By subcutaneous injection preferably in the loose skin on the side of the neck, observing aseptic precautions. The container should be shaken well before doses are withdrawn. 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.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product not subject for prescription.

14. Marketing authorisation numbers and pack sizes

VPA 10387/009/001

Cardboard box containing 1 high density polyethylene bottle of 100 ml or 250 ml sealed with a rubber stopper and closed with an aluminium cap.

Not all pack sizes may be marketed

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Co. Dublin
Ireland
IE – Dublin D18 T3Y1
Tel: +353 (0) 1 256 9800

Manufacturer responsible for batch release:
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

17. Other information

LR (Licensed Retailer)

FURTHER INFORMATION

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. Reduced efficacy against C. *perfringens* type D, 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*, C. *perfringens* types B, C and D and C. *novyi* type B due to the presence of maternally derived antibodies. 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.