

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Covexin 10 suspension for injection for sheep and cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of vaccine contains:

Active substances:

<i>C. perfringens</i> type A toxoid	≥ 0.9 U ³
<i>C. perfringens</i> type B & C (β) toxoid	≥ 12.4 U ¹
<i>C. perfringens</i> type D (ε) toxoid	≥ 5.1 U ¹
<i>C. chauvoei</i> whole culture, inactivated	meets Ph. Eur. ²
<i>C. novyi</i> toxoid	≥ 1.2 U ¹
<i>C. septicum</i> toxoid	≥ 3.6 U ¹
<i>C. tetani</i> toxoid	≥ 2.5 U ¹
<i>C. sordellii</i> toxoid	≥ 0.8 U ¹
<i>C. haemolyticum</i> toxoid	≥ 16.5 U ³

¹ In-house ELISA

² Challenge test according to Ph. Eur.

³ In vitro toxin neutralisation test based on haemolysis of sheep erythrocytes.

Adjuvant:

Alum 3.03 – 4.09 mg Aluminium

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Thiomersal	0.05 – 0.18 mg
Formaldehyde	
Sodium Chloride	
Water for injections	

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 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: 1 year 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: 1 year against *C. tetani* and *C. perfringens* type D

< 1 year 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 1 year 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*.

3.3 Contraindications

Do not use in sick or immunodeficient animals.

3.4 Special warnings

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 3.2).

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

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 swelling ^{1,2,6} , Injection site induration ^{2,6} , Injection site reaction ^{2,6} , Hyperthermia
Common (1 to 10 animals / 100 animals treated):	Injection site abscess ⁶ , Injection site skin discolouration ^{3,6} , Injection site pain ^{4,6}
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reaction ⁵

¹Such a swelling may reach up to a mean value of 6 cm in diameter in sheep and 15 cm (sometimes up to 25 cm) in diameter in cattle.

²Most local reactions will resolve within 3-6 weeks in sheep and in less than 10 weeks in cattle but may persist longer.

³Returns to normal as the local reaction resolves.

⁴For 1 – 2 days post first vaccination.

⁵If such reaction occurs, appropriate treatment such as adrenaline should be administered without delay.

⁶The local reactions do not affect the general health, demeanour, feeding or weight gain of the animals.

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 its local representative> 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:

No side effects other than those described under 3.6 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.

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

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 (see section 3.2 and 3.4).

Re-vaccination scheme:

A single dose should be administered every 6 to 12 months after the basic vaccination scheme (see also point 3.2).

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.

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

In calves and lambs, 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

To be completed nationally.

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* and the toxins of *Clostridium perfringens* type A, *C. perfringens* type B, *C. perfringens* type C, *C. perfringens* type D, *C. novyi*, *C. septicum*, *C. tetani*, *C. sordellii*, and *C. haemolyticum* 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: 2 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.

Keep the bottle in the outer carton.

Protect from light.

5.4 Nature and composition of immediate packaging

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.

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

To be completed nationally.

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: *To be completed nationally.*

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

To be completed nationally.

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

[BE, BG, HR, CY, CZ, DE, EE, FR, EL, HU, IT, LV, LT, LU, NL, PL, PT, RO, ES, SK, SI, UK(NI)]:
Veterinary medicinal product subject to prescription.

[IE]: 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>).

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.

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. PACKAGE SIZE

50 ml

100 ml

4. TARGET SPECIES

Sheep and cattle.

5. INDICATIONS

To be completed nationally.

<For products not subject to veterinary prescription.>

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 8 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Keep the bottle in the outer carton.
Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”
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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

To be completed nationally.

14. MARKETING AUTHORISATION NUMBERS
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To be completed nationally.

15. 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.

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

100 ml

3. TARGET SPECIES

Sheep and cattle.

4. ROUTES OF ADMINISTRATION

Subcutaneous use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 8 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

Do not freeze.

Keep the bottle in the outer carton.

Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER
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To be completed nationally.

9. 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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

C. perfringens type A toxoid; *C. perfringens* type B & C (β) toxoid; *C. perfringens* type D (ϵ) toxoid; *C. chauvoei* whole culture, inactivated; *C. novyi* toxoid; *C. septicum* toxoid; *C. tetani* toxoid; *C. sordellii* toxoid; *C. haemolyticum* toxoid.

50 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 8 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Covexin 10 suspension for injection for sheep and cattle

2. Composition

Each 1 ml of vaccine contains:

Active substances:

<i>C. perfringens</i> type A toxoid	≥ 0.9 U ³
<i>C. perfringens</i> type B & C (β) toxoid	≥ 12.4 U ¹
<i>C. perfringens</i> type D (ε) toxoid	≥ 5.1 U ¹
<i>C. chauvoei</i> whole culture, inactivated	meets Ph. Eur. ²
<i>C. novyi</i> toxoid	≥ 1.2 U ¹
<i>C. septicum</i> toxoid	≥ 3.6 U ¹
<i>C. tetani</i> toxoid	≥ 2.5 U ¹
<i>C. sordellii</i> toxoid	≥ 0.8 U ¹
<i>C. haemolyticum</i> toxoid	≥ 16.5 U ³

¹ In-house ELISA

² Challenge test according to Ph. Eur.

³ In vitro toxin neutralisation test based on haemolysis of sheep erythrocytes.

Adjuvant:

Alum	3.03 – 4.09 mg Aluminium
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Excipient:

Thiomersal	0.05 – 0.18 mg
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Light brown aqueous suspension that settles on storage.

3. Target species

Sheep and cattle.

4. Indications for use

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: 1 year 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: 1 year against *C. tetani* and *C. perfringens* type D
< 1 year 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 1 year 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. Special warnings

Special warnings:

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 for use”).

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 events” 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:

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

Special restrictions for use and special conditions for use:

To be completed nationally.

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 swelling ^{1,2,6} , Injection site induration (thickening/hardening) ^{2,6} , Injection site reaction ^{2,6} , Hyperthermia
Common (1 to 10 animals / 100 animals treated):	Injection site abscess ⁶ , Injection site skin discolouration ^{3,6} , Injection site pain ^{4,6}
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reaction (severe allergic reaction) ⁵

¹Such a swelling may reach up to a mean value of 6 cm in diameter in sheep and 15 cm (sometimes up to 25 cm) in diameter in cattle.

²Most local reactions will resolve within 3-6 weeks in sheep and in less than 10 weeks in cattle but may persist longer.

³Returns to normal as the local reaction resolves.

⁴For 1 – 2 days post first vaccination.

⁵If such reaction occurs, appropriate treatment such as adrenaline should be administered without delay.

⁶The local reactions do not affect the general health, demeanour, feeding or weight gain of the animals.

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 <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes 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.

Basic vaccination scheme:

Two doses should be administered, 4-6 weeks apart (refer to section “Indications for use” and section “Special warnings”).

Re-vaccination scheme:

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

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

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.

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.

Keep the bottle in the outer carton.

Protect from light.

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

BE, BG, HR, CY, CZ, DE, EE, FR, EL, HU, IT, LV, LT, LU, NL, PL, PT, RO, ES, SK, SI, UK(NI):
Veterinary medicinal product subject to prescription.

IE: Veterinary medicinal product not subject to prescription

14. Marketing authorisation numbers and pack sizes

To be completed nationally.

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.

15. Date on which the package leaflet was last revised

To be completed nationally.

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>:

To be completed nationally.

Manufacturer responsible for batch release:

Zoetis Belgium

Rue Laid Burniat 1

1348 Louvain-La-Neuve

Belgium

<Local representative <and contact details to report suspected adverse reactions>:>

To be completed nationally (if needed).

17. Other information

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

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