

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

Active substances	Potency value/mL
<i>C. perfringens</i> type A toxoid	≥0.9 U [#]
<i>C. perfringens</i> type B & C (β) toxoid	≥12.4 IU*
<i>C. perfringens</i> type D (e) toxoid	≥ 5.1U*
<i>C. chauvoei</i> whole culture	meets Ph Eur.**
<i>C. novyi</i> toxoid	≥1.2 IU*
<i>C. septicum</i> toxoid	≥3.6 IU*
<i>C. tetani</i> toxoid	≥2.5 IU*
<i>C.sordellii</i> toxoid	≥0.8 U*
<i>C. haemolyticum</i> toxoid	≥16.5 U [#]
<i>Adjuvant</i>	
Alum	3.03 – 4.09 mg/ml Aluminium
<i>Preservative</i>	
Thiomersal	0.05 – 0.18 mg/ml
Excipient to 1 ml	
Formaldehyde	= 0.5 mg/ml

* In-house ELISA ** Challenge test according to Ph.Eur.

[#] In vitro toxin neutralisation test based on haemolysis of sheep erythrocytes.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.

Light brown aqueous suspension that settles on storage.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep and cattle.

4.2 Indications for use, specifying the 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).

The onset of immunity is two weeks after the primary 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*, *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*.

4.3 Contraindications

None.

4.4 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, 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, see section 4.2).

4.5 Special precautions for use

Special precautions for use in animals

Do not vaccinate sick or immunodeficient animals.

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.

4.6 Adverse reactions (frequency and seriousness)

75 - 100% of animals vaccinated with Covexin 10 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 a mean value of 6 cm in sheep and 15 cm diameter in cattle; occasionally reactions of up to 25cm 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.

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

4.7 Use during pregnancy, lactation or lay

Pregnancy:

No side effects other than those described under 4.6 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.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

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.

Primary vaccination:

Two doses should be administered, 4-6 weeks apart (see section 4.2 and 4.4).

Booster vaccination:

A single dose should be administered at 6 to 12 month intervals (see also point 4.2).

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 primary vaccination course before pregnancy.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In calves and lambs, local reactions may increase slightly if twice the recommended dose is administered (refer to section 4.6).

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Immunological for Bovidae: QI02AB01

Immunological for Ovidae: 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 clostridial infections in young lambs and calves.

6 PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Alum

Thiomersal

Formaldehyde Sodium Chloride (0.85% solution)

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months

Shelf life after first opening the immediate packaging: 8 hours

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Cardboard box with 1 of 50 ml or 100 ml flexible high density polyethylene bottle and closed with a pharmaceutical grade rubber bung held in place with an aluminium seal.

Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park, Loughlinstown
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 May 2005

Date of last renewal: 30 June 2009

10 DATE OF REVISION OF THE TEXT

July 2017