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:

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

Excipient:

Thiomersal	0.05 – 0.18 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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).

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.*

4.3 Contraindications

Do not use in sick or immunodeficient animals.

4.4 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 4.2).

4.5 Special precautions for use

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.

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

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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]

[1]Such 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.
[2]Most local reactions will resolve within 3-6 weeks in sheep and in less than 10 weeks in cattle but may persist longer.
[3]Returns to normal as the local reaction resolves.
[4]For 1 – 2 days post first vaccination.
[5]If such reaction occurs, appropriate treatment such as adrenaline should be administered without delay.
[6]The 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 the national competent authority via the national reporting system. See also section 16 of the package leaflet for contact details.

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 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.

4.9 Amount(s) 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.

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

Re-vaccination scheme:
A single dose should be administered every 6 to 12 months after the basic vaccination scheme (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 basic 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. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Bovidae and Ovidae, inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia) for cattle and sheep, clostridium.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Alum
Thiomersal
Formaldehyde
Sodium Chloride
Water for injections

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

6.4 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.

6.5 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.

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

Medicines should not be disposed of via wastewater.

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

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5120

9. DATE OF FIRST AUTHORISATION

11 March 2003

10. DATE OF REVISION OF THE TEXT

June 2024

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

Approved 22 June 2024
Gavin Hall