1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Covexin 8 Suspension for injection for sheep and cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:	Potency value/Quantity/mL
C. perfringens type B & C (ß) toxoid	≥ 11.6 U/ml*
C. perfringens type D (e) toxoid	≥ 7.1 U/ml*
C. chauvoei whole culture	meets Ph. Eur.**
C. novyi type B anaculture	≥ 2.3 U/ml*
C. septicum toxoid	≥ 3.2 U/ml*
C. tetani toxoid	≥ 1.3 U/ml*
C. haemolyticum anaculture	≥ 10 U/ml[#]
Adjuvant:	
Alum	1.20 - 1.60 mg as aluminium
Preservative:	
Thiomersal	0.12 - 0.18 mg
Other Excipients:	
Formaldehyde	= 0.5 mg

* In house ELISA ** Challenge test according to Ph.Eur.
[#] In vitro toxin neutralisation test based on haemolysis of sheep erythrocytes.
For a 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 from 2 weeks of age. Cattle from 2 weeks of age.

4.2 Indications for use, specifying the target species

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*.

The onset of immunity is two 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 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.

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.

4.5 Special precautions for use

Special precautions for use in animals In the event of an anaphylactic reaction appropriate treatment such as adrenaline should be administered without delay. 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 to be taken by the person administering the veterinary medicinal product to animals In the case of accidental self-injection, encourage bleeding and wash the area immediately with water. If symptoms develop, seek medical attention and show the package leaflet or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

75 - 100% of vaccinated animals 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 6 cm in sheep and 14 cm diameter in cattle. Most local reactions resolve within 3-6 weeks in sheep and in less then 10 weeks in cattle. In up to 17% of animals an abscess may develop. Vaccination may give rise to reactions in the underlying tissues at the injection site. Skin discolouration (which returns to normal as the local reaction resolved) and localised pain for 1-2 days post first vaccination may occur at the injection site.

4.7 Use during pregnancy, lactation or lay

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.

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 decided on a case by case basis.

4.9 Amounts to be administered and administration route

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.

Administration:
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.

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 Covexin 8 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 Covexin 8 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.

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

In calves, 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

Pharmacotherapeutic group and ATC vet code:
Immunologicals for bovidae, cattle, inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia), clostridium
ATC vet code: QI02AB01

Immunologicals for ovidae, sheep, inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia), clostridium
ATC vet code: 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 *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* in young lambs.

To provide passive immunity via the colostrum 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* in calves.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Alum Thiomersal
Sodium chloride (0.85 %w/v) Formaldehyde

6.2 Incompatibilities

Do not mix with any other veterinary medicinal products.

6.3 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

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).Protect from light. Do not freeze.

6.5 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.

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

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)

VPA10387/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th January 2005
Date of last renewal: 13th January 2010

10 DATE OF REVISION OF THE TEXT

July 2017