

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Covexin 8

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Name of ingredient	Potency value/mL
Active ingredients	
<i>C. perfringens</i> type B & C (β) toxoid	$\geq 14.4 U^1$
<i>C. perfringens</i> type D (ϵ) toxoid	$\geq 7.6 U^1$
<i>C. haemolyticum</i>	$\geq 15 U^2$
<i>C. chauvoei</i> whole culture	meets Ph Eur. ³
<i>C. novyi</i> type B toxoid	$\geq 2.7 U^1$
<i>C. septicum</i> toxoid	$\geq 4.6 U^1$
<i>C. tetani</i> toxoid	$\geq 1.7 U^1$
<u>Adjuvant</u>	
Potassium aluminium sulphate	1.20 – 1.60 mg Aluminium
<u>Excipients</u>	
Thiomersal	0.12 – 0.18 mg

For a full list of excipients see section 6.1

¹ In-house ELISA

² *In vitro* toxin neutralisation test based on haemolysis of sheep erythrocytes

³ Challenge according to Ph. Eur.

3. PHARMACEUTICAL FORM

Suspension for injection

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

For the active immunisation of sheep and cattle against diseases associated with infections caused by *C. perfringens* type B, *C. perfringens* type C, *C. perfringens* type D, *C. chauvoei*, *C. novyi* type B, *C. septicum* and *C. haemolyticum* and against tetanus caused by *C. 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 by serology 12 months following the primary course of vaccination.

Sheep: 12 months against *C. perfringens* type B, C and D, *C. novyi* type B, *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 B and C

< 6 months against *C. novyi* type B, *C. septicum*, *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 D, *C. novyi* type B and *C. tetani*. No passive immunity was observed for *C. haemolyticum*.

For calves:

At least 2 weeks for *C. haemolyticum*, at least 8 weeks for *C. septicum* and *C. chauvoei* and at least twelve weeks for *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).

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.

4.5 Special precautions for use

i. Special precautions for use in animals

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

ii. 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 a local reaction develops, seek medical advice showing the package leaflet or the 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 than 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.

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

4.7 Use during pregnancy and lactation

No side effects other than those described under 4.6 are expected when the vaccine is 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 from the concurrent use of this vaccine with any other. 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

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

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

Zero days

5. IMMUNOLOGICAL PROPERTIES

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

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

ATC Vet Codes: QI02AB01 and QI04AB01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium aluminium sulphate
Thiomersal
Formaldehyde

6.2 Incompatibilities (major)

Do not mix with any other medicinal product.

6.3 Shelf life

Unopened vials: 36 months
Opened vials: Part used vials should be discarded within 8 hours of first opening.

6.4 Special precautions for storage

Store and transport between +2°C and +8°C, protected from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Cardboard containing a 100 ml or 250 ml bottle constructed of high density polyethylene 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 product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
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KT22 7LP

8. MARKETING AUHTORISATION NUMBER

Vm 42058/4023

9. DATE OF FIRST AUTHORISATION

19 October 2005

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