CUBOLAC POLICLOSTRIDIAL 7/11 (Reg. No. 1187 ESP)
SUMMARY OF PRODUCT CHARACTERISTICS
Approved by AEMPS: May 2017

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CUBOLAC POLICLOSTRIDIAL 7/11, suspension for injection for bovine and ovine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substances:

α toxoid of *C. perfringens* Type A	≥ 0.3 IU*
ß toxoid *of C. perfringens* Type C	≥ 10 IU*
ε toxoid of *C. perfringens* Type D	≥ 5 IU*
α toxoid of *C. septicum*	≥ 2.5 IU*
α toxoid of *C. novyi* Type B	≥ 3.5 IU*
Toxoid of *C. sordellii*	100% protection**
Inactivated *Cl. chauvoei*	100% protection**

* IU: International units of antitoxin per ml of rabbit serum.
**Level of protection in guinea pigs according to (Ph. Eur.).

Adjuvant:
Aluminium hydroxide (Al^{+3}) 2.8 mg

Excipient:
Thiomersal 0.2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Bovine and ovine.

4.2 Indications for use, specifying the target species

For the active and passive immunisation of bovine and ovine against blackleg, infectious necrotic hepatitis, malignant oedema and enterotoxaemias caused by *C. chauvoei*, *C. novyi* Type B, *C. septicum*, *C. sordellii* and *C. perfringens* Types A, C and D. It also provides immunity against *C. perfringens* Type B, due to the combination of fractions of Type C (β toxin) and Type D (ε toxin).

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Maintain usual aseptic conditions.
Vaccinate healthy and parasite free animals.
Use uninterruptedly once the extraction of the content is initiated.

Safety special precautions to be taken by the person administering the veterinary medicinal product to animals

Accidental inoculation with the vaccine may give rise to the formation of a nodule at the point of injection due to the adjuvant that it contains.

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)

The vaccine contains an adjuvant which very rarely may give rise to the formation of a nodule at the site of injection which disappears in few weeks.

As with other vaccines, hypersensitivity reactions may occur very rarely. In such cases, appropriate antihistaminic treatment should be administered without delay.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

Lactation:
Can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Routes of administration
Subcutaneous or intramuscular

Dosage
Bovine: Administer doses of 5 ml
Ovine: Administer doses of 2 ml

Vaccination schedule

Primary course of immunization: Consists of two doses. The second dose should be administered at least 6 weeks after the first dose.
Pregnant females should be vaccinated 14 days before birth occurs. They will then be able to pass on enough antibodies through the colostrum to enable their offspring to be passively protected against enterotoxemias for the first weeks of life, provided the newborn suck normally within the first hours of life.

Young animals born to unvaccinated mothers: vaccination from two weeks of age.

Young animals born to vaccinated mothers: vaccination from 10-12 weeks of age.

Revaccination: administer a single dose every six months.

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

Not applicable.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated bacterial vaccines for bovine and ovine, vaccine against Clostridium.
ATC vet code: QI02AB01 (bovine) / QI04AB01 (ovine).

For active and/or passive immunisation against the following diseases caused by clostridia:

C. perfringens Type A	Haemorrhagic enteritis and yellow disease in lambs (passive and active immunisation)
C. perfringens Type B	Lamb dysentery (passive immunisation)
C. perfringens Types B and C	Calf dysentery (passive immunisation)
C. perfringens Type C	Haemorrhagic enteritis and fulminating enterotoxaemia (passive and active immunisation)

C. perfringens Type D	Pulpy kidney (passive and active immunisation)
C. septicum	Malignant oedema and braxy (active immunisation)
C. novyi Type B	Infectious necrotic hepatitis (active immunisation)
C. sordellii	Cephalic oedema or big head and enterotoxaemias (active and passive immunisation)
C. chauvoei	Emphysematous gangrene or symptomatic anthrax (active immunisation)

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Thiomersal
Water for injections

6.2 Major incompatibilities

None known.

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: Use immediately.

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

High density polyethylene vials of 100 ml and 250 ml with perforable butyl rubber stopper and aluminium seal.

Pack sizes:
Box with 1 vial of 100 ml.
Box with 1 vial of 250 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

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

CZ Veterinaria, S.A.
La Relva s/n - Torneiros
36410 Porriño (Spain)

8. MARKETING AUTHORISATION NUMBER(S)

1187 ESP

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th of October of 1997.
Date of last renewal: 16th of May of 2008.

10 DATE OF REVISION OF THE TEXT

May of 2017

PROHIBITION OF SALE, SUPPLY AND/OR USE

Dispensation conditions: **Medicinal product subject to veterinary prescription.**
Administration conditions: **Administration under control or supervision of a veterinary surgeon.**