COGLAVAX®

Product information

CONTENTS

1. NAME OF THE IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCT

COGLAVAX

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition for a 2-ml vaccinal dose

Antigens in sufficient quantity to obtain the following level of antibodies and level of protection in the serum of control animal

Clostridium perfringens (type A, C, D):

Alpha toxoid	not significantly lower than 2.0 IU/ml
Beta toxoid	not significantly lower than 10.0 IU/ml
Epsilon toxoid	not significantly lower than 5.0 IU/ml
Toxoid of *Clostridium septicum*	not significantly lower than 2.5 IU/ml
Toxoid of *Clostridium novyi B (oedematiens)*	not significantly lower than 3.5 IU/ml
Toxoid of *Clostridium tetani*	not significantly lower than 2.5 IU/ml
Anaculture of *Clostridium chauvoei*	90 % protection

Aluminium hydroxide as Al(OH)3 (adjuvant)	0.6 – 0.8 %
Formaldehyde as preservative	≤ 0.05 %

3. PHARMACEUTICAL FORM

Injectable suspension.

4. IMMUNOLOGICAL PROPERTIES

The vaccine stimulates immunity in the target species against enterotoxaemia type diseases, gas gangrene type diseases and intoxication type disease due to Clostridium perfringens A ,B, C, D, C. novyi (oedematiens), septicum, tetani and chauvoei.

5. CLINICAL PARTICULARS

5.1 | Target species

Cattle, sheep, goats

5.2 | Indications for use, specifying the target species

Prevention, by active immunization against enterotoxaemia due to C. perfringens A ,B, C, D and clostridial infections due to C. novyi (oedematiens), septicum, tetani and chauvoei:

- Enterotoxaemia in adult sheep
- Bacillary dysentery of calves and lambs
- Pulpy kidney disease
- Haemorrhagic enteritis in lambs and kids
- Necrotic hepatitis
- Bradsot or malignant oedema of abomasum
- Blackleg
- Gas gangrene
- Tetanus

5.3 | Contraindications

Nil

5.4 | Undesirable effects

A mild local reaction at the injection site is normal. This subcutaneous oedema disappears in a few weeks.

5.5 | Special precautions for use

- Observe the usual aseptic precaution.
- Shake well before use.
- As goats are very sensitive to parenteral injections, it is advised to carry out a preliminary test on few animals, or to prevent possible shock by suitable measures (high-water diet, anti-histaminic administration).
- Administer only to healthy animals.
- In case of accidental injection to the user, consult immediately a doctor.
- Keep out of reach of children.

5.6 | Use during pregnancy and lactation

See point 5.7.

5.7 | Interactions with other medicaments and other forms of interaction

Nil.

5.8 | Posology and method of administration

Subcutaneous injection

Sheep and goats:	2 ml at any time
Calves weighing less than 100 kg:	2 ml
Calves weighing more than 100 kg and cattle:	4 ml

- Protocol of vaccination:
  - First vaccination: 2 injections at 4 weeks interval
  - Booster: one year after the last injection

- Pregnant animals:
  - In order to obtain an optimal level of colostral antibodies, the second injection of the first vaccination or the booster injection is applied not later than 2 weeks before expected parturition.

- Youngs from vaccinated mothers: vaccination from the 8th week.
- Youngs from non-vaccinated mothers: vaccination from the 3rd week.

5.9 | Overdose (symptoms, emergency procedure, antidotes)

The administration of an overdose (double dosage) to sheep, has been carried out.
No significant hyperthermia, or serious inflammatory local reaction was observed.
A mild oedematic reaction at the site of injection was observed in sheep and rabbits received a double dosage. This reaction disappeared in a few weeks.

5.10 | Special warnings for each target species

As goats are very sensitive to parenteral injections, it is advised to carry out a preliminary test on few animals, or to prevent possible shock by suitable measures (high-water diet, anti-histaminic administration).

5.11 | Withdrawal periods

Nil

5.12 | Special precautions to be taken by the user

In case of accidental injection into the user, consult immediately a doctor.

6. PHARMACEUTICAL PARTICULARS

Injectable suspension.

6.1 | Incompatibilities (major)

Unknown

6.2 | Shelf life

24 months

After first opening of the container, it is recommended to use the vaccine within 8 hours.

6.3 | Special precautions for storage

The product must be stored between +2°C and +8°C protected from light.
Do not freeze.

6.4 | Nature and contents of container

Low density polyethylene containers: 50, 100, 250, 500 ml.

6.5 | Special precautions for the disposal of unused product or waste materials, if any

The unused products and the waste materials must be destroyed according to the national rules for treatment of medicinal waste materials.