PACKAGE INSERT – ENGLISH

FOR ANIMAL USE ONLY

COGLAVAX®

Reg. No. G3684 (Act 36/1947)
Namibia: NS0 Reg. No. V06/24.4/180 (Act 13/2003)
Zambia Reg. No. 346/717V (Act 3/2013)

Vaccine Suspension

A polyvalent inactivated vaccine for the prevention of Clostridial infections in cattle and sheep.

STORAGE

Store between 2 - 8 °C.
Protect from light.
Do not freeze

COMPOSITION

This vaccine contains antigens in sufficient quantities to obtain the following levels of antibodies in the serum of control animals:
Including:

Cl. perfringens type A, C and D		
Alpha toxoid		2 IU/mℓ
Beta toxoid		10 IU/mℓ
Epsilon toxoid		5 IU/mℓ
Cl. septicum toxoid		2,5 IU/mℓ
Cl.novyi type B Alpha toxoid		3,5 IU/mℓ
Cl. tetani toxoid		2,5 IU/mℓ
Cl. chauvoei		*90* % protection in guinea pigs
Adjuvant: Aluminium hydroxide as $Al(OH)_3$	q.s.	0,6 - 0,8 %
Preservative: Formaldehyde	q.s.	< 0,05 %

WARNINGS

- Meat withdrawal period: 21 days
- Vaccinate healthy animals only.
- The vaccine contains an adjuvant which may result in a mild, temporary local reaction at the site of injection.
- A small number of individuals may fail to develop an immune response in any group of animals as a result of immuno-incompetence or for other reasons.
- As with most inactivated vaccines, significant development of immunity cannot be expected until two weeks after the second dose of the vaccination course.

During the vaccination process, stressing of the animals should be avoided, particularly during the later stages of pregnancy when there is an increased risk of induction of abortion and metabolic disease conditions.

- Occasional hypersensitivity reactions may occur.
- Keep out of reach of children, uninformed persons and animals.
- Although this vaccine has been extensively tested under a large variety of conditions, failure thereof may ensue as a result of a wide range of reasons. If this is suspected, seek veterinary advice and inform the registration holder.

PRECAUTIONS

- Observe the usual aseptic precautions in the administration of this vaccine.
- Do not mix with any other vaccine.
- In case of accidental self-injection to the user, immediately consult a doctor.
- Destroy any unused vaccine and dispose of all the vaccine containers and disposable equipment after use in accordance with National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008)
- It is good vaccination practice not to allow vaccine to come into contact with human eyes or mucous membranes.
- Wash and disinfect hands with a disinfectant after vaccination.

DIRECTIONS FOR USE: USE ONLY AS DIRECTED

Shake well before use.

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

Administration is by subcutaneous injection in the loose skin on the upper side of the neck.

No alcohol or any other disinfectants should be used for sterilization of the needles and syringes.

Dosage

SUGGESTED VACCINATION SCHEDULE			
DOSAGE	**FIRST VACCINATIONS**		**ANNUAL RE-VACCINATION**
	Dose/time of the 1st injection	**Dose/time of the 2nd injection (Booster)**	
SHEEP:			
Non pregnant ewes, rams	2 mℓ at any time	2 mℓ, 4 - 6 weeks after the 1st injection.	2 mℓ, 1 year after the last injection or 4-6 weeks prior to challenge period.
Pregnant ewes	2 mℓ, 4 - 6 weeks before the expected lambing date.	2 mℓ, 4 weeks after the 1st injection and not later than 4 - 6 weeks before the expected lambing date	2 mℓ, 1 year after the last injection or not later than 4 - 6 weeks before the expected lambing date.
Lambs	2 mℓ at 4 - 6 weeks of age (unvaccinated). If the ewe was previously vaccinated, start the vaccination at 8 weeks of age.	2 mℓ, 4 - 6 weeks after the 1st injection.	2 mℓ, 1 year after the last injection or 4 - 6 weeks prior to challenge period.
CATTLE:			
Calves weighing less than 100 kg	2 mℓ at any time.	2 mℓ, 4 - 6 weeks after the 1st injection.	4 mℓ, 1 year after the last booster injection or not later than 4 - 6 weeks before the risk period.
Calves and Adult cattle	4 mℓ at any time.	4 mℓ, 4 - 6 weeks after the 1st injection.	4 mℓ, 1 year after the last booster injection or 4 - 6 weeks prior to challenge period.

EFFICACY

Cattle and Sheep:

For the active immunization of cattle and sheep against infections caused by Alpha, Beta and Epsilon toxins from *Cl. perfringens* A, *C* and D.
Cl. novyi B Alpha toxin, *Cl. septicum, Cl. tetani* and *Cl. chauvoei* in the following bacterial disease conditions:
Pulpy Kidney Disease in sheep
Blackquarter in cattle and sheep
Gas gangrene in cattle and sheep
Tetanus in cattle and sheep
Malignant ~~Oedema~~ Edema in cattle and sheep (Swelled Head)
Enterotoxaemia (Bloodgut) in cattle; Redgut and Lamb Dysentery in sheep and lambs

IDENTIFICATION

Clear brown vaccine suspension.

PRESENTATION

100 mℓ, 250 mℓ and 500 mℓ, in plastic containers

REGISTRATION HOLDER

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MANUFACTURER

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