



Inactivated polyvalent bacterial vaccine, against enterotoxemia, gas gangrene, pasteurellosis and septicemic colibacillosis for cattle, sheep and goats

COMPOSITION:

Each dose of 1 ml contains:

- *Cl.perfringens* type B - β toxoid, at least 10 IU of antitoxin*
- *Cl.perfringens* type D - ϵ toxoid, at least 5 IU of antitoxin*
- *Cl.septicum* toxoid, at least 2.5 IU of antitoxin*
- *Cl.sordellii* toxoid, at least 5 IU of antitoxin**
- Bacterial cells and leukotoxin of *Mannheimia haemolytica* serotypes A1 and A2 ≥ 0.6 ELISA.U***
- *Pasteurella multocida* A $\geq 80\%$ of protection****
- *Escherichia Coli* serotype O78 $\geq 90\%$ of protection****
- Aluminium (as hydroxide), 2.1 mg + 0.2
- Free formaldehyde, at most 0.5 mg
- Excipient s.q.f. 1 ml.

(*) IU: antibody titre obtained according to the European Pharmacopoeia.

(**) IU: antibody titre obtained according to the American Pharmacopoeia.

(***) 1 ELISA.U: s.q. to obtain a seroconversion index (by ELISA) of 1 log10 in guinea-pigs after 2 administrations of the vaccine.

(****) % PC: Rate of protection of immunized mice against a challenge.

INDICATIONS:

In cattle, sheep and goats:

Active immunization against enterotoxaemia, gas gangrene, pasteurellosis and septicemic colibacillosis:

- **Enterotoxaemia:** *Cl. perfringens* type B (lamb dysentery), *Cl. perfringens* type D (pulpy kidney disease) and *Cl. sordellii* (intestinal toxi-infection).
- **Gas gangrene:** *Clostridium septicum* (Braxy).
- **Pasteurellosis:** *Mannheimia haemolytica* serotypes A1 and A2 and *Pasteurella multocida* A.
- **Septicemic colibacillosis:** *Escherichia Coli* serotype O78.

SPECIAL WARNINGS FOR EACH TARGET SPECIES:

Vaccinate only healthy animals.

SPECIAL PRECAUTIONS FOR USE IN ANIMALS:

Due to the known sensitivity of pregnant goats, it is recommended to handle them carefully.

SPECIAL PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE VETERINARY MEDICINAL PRODUCT TO ANIMALS:

- Avoid contact with eyes, hands and clothing
- In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

OTHER PRECAUTIONS:

- Use the normal conditions of animal handling.
- Avoid injecting the vaccine at too low temperature.
- Use for the injection of the vaccine suspension sterile equipment free from any antiseptic and/or disinfectant.
- Disinfect the site of inoculation and avoid inadvertent trauma.



ADVERSE REACTIONS:

The vaccine can cause the apparition of a nodule at the injection site, of the size of a hazelnut or a walnut, disappearing within 3 to 4 weeks after vaccination. Hypersensitivity reactions may appear in animals previously sensitized by the infection. In an infected environment, test the sensitivity of few animals before generalizing the vaccination to the whole herd.

USE DURING PREGNANCY OR LACTATION:

This vaccine is indicated for administration to pregnant females at 6 to 4 weeks before the expected date of parturition.

No contra-indications for lactating females.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:

No information is available on the safety and efficacy of this vaccine associated with any other veterinary medicinal product. The decision to use this vaccine before or after any other veterinary medicinal product needs to be made on a case by case basis.

DOSAGE AND ADMINISTRATION:

- Apply aseptic conditions.
- Shake well before use.

Route of administration:

Administer the vaccine subcutaneously or intramuscularly on the side of the neck or behind the shoulder.

Vaccine dose:

- Sheep and goats:
- Young animals, less than 30 kg : 1 ml.
- Adult animals, over 30 kg : 2 ml.
- Cattle : 4 ml.

Vaccination schedule:

- Primary vaccination: 2 injections at 4 weeks interval.
- Booster : One annual injection.

Pregnant females:

To provide passive protection of newborns through colostrum, the second injection of the primary vaccination or booster injection dose should be administered during the last third of gestation between 6 and 4 weeks before the expected date of parturition.

Young animals:

- From unvaccinated mothers: vaccination from the second week of age.
- From vaccinated mothers : vaccination from 8 weeks of age.

OVERDOSE (SYMPTOMS, EMERGENCY PROCEDURES, ANTIDOTES) IF NECESSARY:

No adverse reactions other than those mentioned in section "Adverse reactions" were observed after the administration of an overdose of vaccine.

WITHDRAWAL TIME:

Zero day.

INCOMPATIBILITIES:

Do not mix with other veterinary drugs.

SPECIAL PRECAUTIONS FOR STORAGE:

Store and transport at a temperature between +2 °C and +8 °C.

Protect from light. Do not freeze.

After opening, use the vaccine immediately.

PRESENTATION (S):

Bottles of 50 ml, 100 ml, 250 ml and 500 ml.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED MEDICINAL PRODUCTS 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.