



# Botivac<sup>®</sup>

## Inactivated suspension for injection adsorbed vaccine against Botulism diseases

### STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS:

- Active substance:  
Each 1 ml immunizing dose contains sufficient amount of toxoids and ana-cultures to obtain:
  - *Clostridium botulinum* type C  $\geq$  80% protection.
  - *Clostridium botulinum* type D  $\geq$  80% protection.
- Other ingredients:  
Aluminum hydroxide gel: < 4 mg / ml.

### INDICATIONS:

Botivac vaccine is used to protect cattle, sheep and goats against botulism. Onset of immunity: 21 days post vaccination. Duration of immunity: at least 1 year.

### CONTRAINDICATIONS:

Do not vaccinate sick or stressed animals. Botivac should not be used in lambs, kids, calves less than 3 weeks of age due to the possible immunological incompetence of the very young newborn animal and competition from any maternally derived colostral antibodies.

### ADVERSE REACTIONS:

None.  
If you notice any side effects, please inform your veterinarian.

### TARGET SPECIES:

Sheep, goats and cattle.

### DOSAGE:

- Administer subcutaneously, (preferably in the elbow region for sheep & goats and under the skin of the neck just in front of the shoulders for cattle) as follows:  
Sheep & goats: 1 ml  
Cattle: 2 ml
- Vaccination of cattle:  
Vaccinate with one recommended dose (2 ml) at any age.
  - First vaccination: vaccinate with one recommended dose starting at 3 months of age, revaccinate after 4-6 weeks of first vaccination.
  - Booster vaccination: vaccinate with one recommended dose annually.
- Vaccination of sheep & goats:
  - First vaccination: vaccinate with one recommended dose at any age, revaccinate after 4-6 weeks of first vaccination.
  - Booster vaccination: vaccinate with one recommended dose annually.

### ADVICE ON CORRECT ADMINISTRATION:

- Shake well before use.
- Apply usual aseptic procedures.
- Avoid stress when vaccinating.

### WITHDRAWAL PERIOD:

Zero days.

### SPECIAL STORAGE PRECAUTIONS:

- Store in a refrigerator (2°C-8°C).
- Protect from direct sunlight.
- Do not freeze.
- Keep out of the reach and sight of children.
- Shelf life after first opening: Use the vaccine within 8 hours after first opening.
- The vaccine remains stable for 2 years from production date stated on the label under the recommended storage conditions.

### SPECIAL WARNING(S):

**Special warnings for each target species:**

Vaccinate healthy animals only.

**Special precautions for use in animals:**

Not applicable.

**Special precautions to be taken by the person administering the medicinal product to animals:**

Although Botivac vaccine is an inactivated vaccine and is not pathogenic for humans; care should be taken to avoid accidental injection. Should accidental injection occur immediate medical care should be sought.

**Use during pregnancy, lactation, fertility:**

Can be used during pregnancy, lactation and breeding.

**Interaction with other medicinal products and other forms of interaction:**

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before and after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

**Overdose:**

2X dose of a vaccine:

None.

If you notice any side effects, please inform your veterinarian.

### SPECIAL PRECAUTIONS FOR DISPOSAL:

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

### MANUFACTURING AUTHORIZATION HOLDER AND MANUFACTURED BY:

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