FOR VETERINARY USE ONLY

BOTUDOLL

INACTIVATED BOTULISM VACCINE

Dollvet

SOLUTION FOR INJECTION

COMPOSITION:

Ingredients	Quantity
Cl. botulinum type C	≥ 80% Protection*
Cl. botulinum type D	≥ 80% Protection*
Aluminum hydroxide gel	15%
Formaldehyde (of 37%)	≤ 0,8%
Phenol (of 80%)	≤ 0,32%

* Antitoxin potency where at least 80% of the vaccinated mice are protected against 25 paralytic doses of Cl. botulinum type C and type D toxins.

INDICATIONS:

BOTUDOLL is used to protect cattle, sheep and goats against Botulism, caused by Cl. botulinum type C and Cl. botulinum type D.

ADMINISTRATION METHOD AND DOSAGE:

The vaccine is administered with subcutaneous injection of 2 ml into the immobile area behind the shoulder in cattle, and 1 ml into the immobile area on axilla in sheep and goats. Animals to be vaccinated for the first time, should be given a second injection 4-6 weeks later. In order to maintain a high level of immunity, single-dose vaccinations should be administered every year. In predisposed conditions of high risk of disease, a single dose vaccination is recommended after 6 months. Cattle, sheep and goats can be vaccinated as of 3 months of age.

SPECIFIC CLINICAL INFORMATION AND WARNINGS FOR TARGET SPECIES:

Pregnant goats should not be vaccinated.

ADVERSE REACTIONS:

In rare cases of anaphylactic shock developing shortly after vaccination in susceptible animals, adrenergic and antihistaminic preparations should be administered. Nodules, varying in size from nuts to walnuts, that are seen at the vaccine administration site, then disappear, are normal vaccine reactions.

INTERACTION WITH OTHER MEDICINAL PRODUCTS:

No information is available on the safety and efficacy of this vaccine for use with other biological products.

OVERDOSE SYMPTOMS, EMERGENCY PROCEDURES AND ANTIDOTES:

The vaccine is an inactivated one. Safety studies in booster applications have shown that it is safe.

WITHDRAWAL PERIODS:

0 days.

CONTRAINDICATIONS:

BOTUDOLL is not recommended to be adminstered to infected animals or those in incubation period.

GENERAL WARNINGS:

“Consult a veterinarian before use”
“Keep out of reach of children”
“Consult a veterinarian upon an unexpected effect”

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PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE VACCINE AND RECOMMENDATIONS FOR VETERINARIANS:

- Vaccines should be stored at +2/+8ºC and shaken well before use. Remaining vaccines should not be used.
- Asepsis and antisepsis principles should be followed during administration.
- BOTUDOLL should only be administered by a Veterinarian or a veterinary technician under the supervision of a Veterinarian.

STORAGE CONDITIONS AND SHELF LIFE:

Should be stored at + 2/8ºC, and in the dark. Do not freeze. Shelf life is 24 months. Opened vials should be used within 6-8 hours.

DISPOSAL OF WASTE/UNUSED PRODUCTS AND RECOMMENDATIONS FOR NON-TARGET SPECIES:

Unused or opened but not completely used vaccines are disposed of as medical waste, according to the provisions of the applicable waste regulations.

PRESENTATION:

The vaccine is packaged in 20, 50, and 100 ml amber colored type II glass bottles, and 50, 100, 200 and 250 ml plastic bottles, containing 10, 25, 50, 100 and 125 cattle doses or 20, 50, 100, 200 and 250 sheep and goat doses. Glass and plastic bottles are labeled as closed with the same butyl stoppers and aluminum caps. Vaccine vials are available on the market as 20 ml, 50 ml, 100 ml, 200 ml and 250 ml glass and plastic vials either placed in single-unit cardboard boxes or unboxed packaged in styrofoam. Not all forms of packaging may be placed on the market.

LEAFLET APPROVAL DATE: 27.11.2020

DATE OF MARKETING AUTHORIZATION ISSUED BY MINISTRY OF AGRICULTURE AND FORESTRY: 25.06.2007

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:
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