





LYOPHILIZED BRUCELLA ABORTUS \$19 VACCINE

BRUDOLL-AGenç is a Brucella abortus S 19 vaccine prepared against brucellosis of cattle

PHARMACEUTICAL FORM:

Vaccine consisting of lyophilized Attenuated Brucella abortus S 19 strain pellet and dilution

COMPOSITION:

One dose of vaccine (1 ml):

	Attenuated Brucella abortus S 19	40-120 x 10 ⁹ CFU/dose
	Enzymatic digest of Proteins / Casein	0,125 mg/dose
4	Sukroz	0,25 mg/dose
	Sodyum glutamate	0,05 mg/dose
	HEPES	0,01 mmol/dose

INDICATIONS:

It is applied for 3-6 months old female calves for protective purposes against brucellosis.

CONTRAINDICATIONS:

It is not used in males and animals older than 6 months.

ADVERSE EFFECTS:

Small stiff nodules that can sometimes be seen at the injection area and a temporary rise in body temperature are considered as normal vaccine reactions.

TARGET SPECIES: 3-6 months old female calves

METHOD OF ADMINISTRATION AND DOSE:

The lyophilized vaccine is homogenized with 3-4 ml of diluent drawn into a sterile syringe and it is added to the diluent with the same syringe, mixed and made ready for administration. The mixing process of the vaccine vial should be repeated until the vaccination is concluded. It is administered to 3-6 month old female calves as 1 ml subcutaneous from the left side of the neck. A separate needle should be used for each animal in vaccination. It is not used in males and animals older than 6 months.

WARNINGS:

The diluted vaccine should be used within 6 hours as maximum. Vaccines exposed to high temperatures and sunlight should not be used. Animals to be vaccinated should be healthy. Asepsis and antisepsis should be taken into consideration in vaccine administrations. BRUDOLL-A Genc should be applied only by veterinarians or veterinary technicians under the supervision of a veterinarians.

ONLY USED FOR ANIMAL HEALTH



INJECTABLE SUSPENSION LYOPHILIZATE



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

Brucella abortus S 19 is capable of causing disease in humans, although it is an attenuated strain. Therefore, appropriate biosafety measures complying with the bacteria should be taken. Gloves should be used during vaccination and an antiseptic solution should be available when needed. During application of the vaccine and diluted vaccine, improper application, eye and skin contamination should be avoided. In case of accidental contact, medical intervention should be sought.

WITHDRAWAL PERIOD FOR ANIMALS ORIGIN PRODUCTS:

It is recommended that the vaccinated animals should not be slaughtered for 90 days.

STORAGE CONDITIONS: The vaccine should be stored at 2 / 8°C and in the dark.

PRESENTATION:

5 doses of the lyophilized powder in type I glass vials and 5 ml diluent vials, each 5 vaccine vials and diluent vials are packaged in plastic box, or packaged in styrofoam in unboxed form: With type I glass vial containing 10 doses of lyophilized powder and 10 ml of diluent. With type I glass vial containing 20 doses of lyophilized powder and 20 ml of diluent.

SHELF LIFE: 24 months (2 years)

DISPOSAL OF WASTE AND UNUSED PRODUCTS:

Vaccines that are diluted and unused are disposed of by boiling for 15 minutes. Unused vaccines in lyophilized form are returned to the manufacturer for disposal.

[&]quot;In case of an unexpected effect, consult the veterinarian"



THE MARKETING AUTHORIZATION ISSUED BY MINISTRY OF AGRICULTURE AND FORESTRY. DATE

AND NUMBER: 05 05 2009

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:

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[&]quot;Keep out of reach of children"