FOR VETERINARY USE ONLY

BRUDOLL-A Conjunctival

BRUCELLA ABORTUS S19 EYE DROP VACCINE

Dollvet

LYOPHILISATE FOR CONJUNCTIVAL SUSPENSION AND RECONSTITUTION SOLVENT

COMPOSITION:

Each dose of vaccine (50 µl (1 drop)) consists of following ingredients

Active ingredients	Quantity	Function
Attenuated *Brucella abortus S19* strain	5-10x10^{9} CFU/dose	Immunizing antigen
Excipients		
Enzymatic digestion of proteins/Casein	0.8 mg/dose	Preservative
Sucrose	1.6 mg/dose	
Sodium glutamate	0.32 mg/dose	
HEPES	0.01 mmol/dose	Tampon

Reconstitution Solvent

Ingredients	Quantity	Function
Patent blue V	0.005 mg/dose	Reconstitution Solvent
Water for Injection	50 µl q.s.	

IMMUNOLOGICAL PROPERTIES:

Pharmacotherapeutic group: Attenuated, lyophilized, bovine *Brucella abortus S-19* eye drop vaccine
ATC Vet Code: QI02AE

INDICATIONS:

BRUDOLL-A Conjunctival: attenuated lyophilized *Brucella abortus S19* eye drop vaccine used for prophylaxis against bovine brucellosis.

METHOD OF ADMINISTRATION AND DOSAGE:

The lyophilized vaccine is homogenized with the accompanying blue reconstitution solvent. The calibrated dropper is mounted on the bottle of the diluted vaccine before use. Female calves are vaccinated by conjunctival administration of 50±2µl (1 drop).

CLINICAL PARTICULARS AND SPECIAL WARNINGS FOR TARGET SPECIES:

Female calves should be vaccinated from 3 months of age. Animals vaccinated for the first time should be revaccinated after 6-8 months.
Use in pregnancy and lactation: It is not recommended for use in pregnant cattle as it may cause abortion. However, it can be applied to animals in the last months of pregnancy in cases of disease occurs.

ADVERSE REACTIONS

Adrenergic and antihistamine preparations should be administered against anaphylactic shock that may occur shortly after vaccination in susceptible animals, although this is rare. It may cause false positive reactions in serological tests in vaccinated animals, which may last up to 6 months.

INTERACTION WITH OTHER MEDICINAL PRODUCTS:

The safety and efficacy of using the product with other products is not known.

OVERDOSE, SYMPTOMS IF ANY, EMERGENCY PROCEDURES AND ANTIDOTES:

It is safe at a dose of 10 times the normal application dose.

WITHDRAWAL PERIOD:

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

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CONTRAINDICATIONS:
It is not recommended for use in male cattle and pregnant cattle.

GENERAL WARNINGS:
"Keep out of reach of children"
"Consult your veterinarian before use and in case of an unexpected effect"

PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE VACCINE AND RECOMMENDATIONS FOR VETERINARIANS:
-Infected animals, animals suspected of infection during the incubation period, and animals under stress should not be vaccinated.
- When the vaccine is to be used, the lyophilized pellet should be thoroughly dissolved with the reconstitution solvent using sterile syringes and the vaccine bottle should be shaken gently before each use.
- The vaccine should be brought to room temperature before administration.
- Asepsis and antisepsis rules should be followed in vaccine administration.
- *Brucella abortus S19* is an attenuated strain but is capable of causing disease in humans. Therefore, appropriate biosecurity measures should be taken when working with the bacteria. In case of injuries that may occur during the administration, the area should be cleaned and disinfected.
- The vaccine should only be administered by veterinarians or veterinary health technicians under the supervision of veterinarians.

STORAGE CONDITIONS AND SHELF LIFE:
Conjunctival lyophilisate: Store at +2/+8°C and in the dark. Do not freeze. Shelf life is 24 months.
Reconstitution solvent: Store in the dark and at temperatures below 25°C. Do not freeze.
Shelf life is 24 months. The reconstituted vaccine should be used within 6 hours.

DISPOSAL OF WASTE AND RECOMMENDATIONS FOR NON-TARGET SPECIES:
Following use of the products, residual materials should be destroyed by boiling, burning or immersing in a suitable disinfectant.

PRESENTATION:
The vaccine is packaged in 4R or 6R Type I colorless glass vials containing lyophilized pellets of 25 and 50 doses: the reconstitution solvent is packaged in 6R Type II colorless glass vials as 1.25 and 2.5 ml. The glass vials are labeled and closed with a bromobutyl stopper and aluminum cap. Lyophilized pellet, reconstitution solvent and dropper are presented to the market together in a box.

LEAFLET APPROVAL DATE: 28.02.2012

DATE OF MARKETING AUTHORIZATION ISSUED BY MINISTRY OF AGRICULTURE AND FORESTRY: 28.02.2012

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