

FOR VETERINARY USE ONLY

BRUDOLL-M
Conjunctival

BRUCELLA MELITENSIS REV 1 EYE DROP VACCINE



Dollvet

LYOPHILISATE FOR SUSPENSION FOR INJECTION AND SOLVENT

BRUDOLL-M Conjunctival is a live attenuated and lyophilized *Brucella melitensis* Rev-1 eye drop vaccine prepared against brucellosis in sheep and goats.

COMPOSITION:

Each dose of vaccine (1 drop: 50µl):

<i>Attenuated Brucella melitensis</i> Rev 1	0,5-2 x 10 ⁹ CFU/dose
<i>Enzymatic digest of Proteins / Casein</i>	0,8 mg/dose
Sucrose	1,6 mg/dose
Sodium glutamate	0,32 mg/dose
HEPES	0,01 mmol/dose

INDICATIONS:

Administered for protection against brucellosis in healthy female and male lambs, and kids of 3-6 months old. It is also administered to nonpregnant adult females and adult males during countrywide mass vaccinations or when needed due to disease risk.

CONTRAINDICATIONS:

Not to be administered to pregnant animals as it may cause abortion. However, it can be administered in the last months of pregnancy at an outbreak of disease.

ADVERSE REACTIONS:

In rare cases of anaphylactic shock developing shortly after vaccination in susceptible animals, adrenergic and antihistaminic preparations should be administered. In vaccinated animals, it may cause false positive reactions that can last up to 6 months in serological tests.

TARGET SPECIES:

Sheep and goats

ADMINISTRATION METHOD AND ROUTE:

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.

Healthy female and male lambs, and kids of 3-6 months old are vaccinated by conjunctival administration of 50-2µl (1 drop). The administration method is the same also for adult male and female animals.

WARNINGS:

- * The reconstituted vaccine should be used within 6 hours at the latest.
- * Vaccines exposed to high temperatures or sunlight and packaging integrity broken should not be used.
- * Animals to be vaccinated must be in good health.
- * Asepsis and antisepsis principles should be followed during administration.
- * BRUDOLL-M Conjunctival should only be administered by a Veterinarian or a veterinary technician under the supervision of a Veterinarian.

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

Although *Brucella melitensis* Rev-1 is an attenuated strain, it is capable of causing disease in humans. Therefore, it is necessary to work with bacteria by taking appropriate biosafety measures. Gloves should be used during vaccination, and an antiseptic solution should be available to be used when needed. Maladministration and eye and skin contamination should be avoided during reconstitution and vaccination. In case of an accidental contact, medical attention should be sought.

WITHDRAWAL PERIODS:

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

STORAGE CONDITIONS:

Store refrigerated at +2/+8°C

PRESENTATION:

25 doses of lyophilized vaccine with 1.25 ml solvent for reconstitution and dropper

50 doses of lyophilized vaccine with 2.5 ml solvent for reconstitution and dropper

100 doses of lyophilized vaccine with 5 ml solvent for reconstitution and dropper

200 doses of lyophilized vaccine with 10 ml solvent for reconstitution and dropper

SHELF LIFE:

24 months (2 years)

DISPOSAL PRECAUTIONS:

Reconstituted and unused vaccines are disposed of by boiling for 15 minutes.

LEAFLET APPROVAL DATE: 28.02.2012

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

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:

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