

FOR VETERINARY USE ONLY

BRUDOLL^{GENÇ}-M

LYOPHILIZED BRUCELLA MELITENSIS REV 1 VACCINE



Dollvet

LYOPHILISATE FOR SUSPENSION FOR INJECTION

BRUDOLL-M Genç is a *Brucella melitensis* Rev-1 vaccine prepared against brucellosis in sheep and goats.

PHARMACEUTICAL FORM:

Vaccine consisting of live lyophilized pellets of attenuated *Brucella melitensis* Rev-1 vaccine strain and reconstitution solvent.

COMPOSITION:

Each dose of vaccine (1 ml):

Attenuated <i>Brucella melitensis</i> Rev 1	0,5-4 x 10 ⁹ CFU/dose
Enzymatic digest of Proteins / Casein	0,125 mg/dose
Sucrose	0,25 mg/dose
Sodium glutamate	0,05 mg/dose
HEPES	0,01 mmol/dose

INDICATIONS:

Administered for protection against brucellosis in sheep and goats of 4-6 months old.

CONTRAINDICATIONS:

Not to be administered to pregnant animals and ones in incubation period and to adult males.

ADVERSE REACTIONS:

Rare cases of small and hard swellings at the injection site and a temporary rise in body temperature are considered as normal vaccine reactions.

TARGET SPECIES:

Sheep and goats.

ADMINISTRATION METHOD AND ROUTE:

The lyophilized vaccine is homogenized with 3-4 ml reconstitution solvent drawn into a sterile syringe, added to the reconstitution solvent with the same syringe, mixed well, and thus becomes ready for administration. This mixing process should be repeated throughout the vaccination process.

It is administered by subcutaneous injection of 1 ml to 4-6 months old male and female lambs, and kids into the hairless skin of the axilla. A separate needle should be used for each animal. It is not administered to animals older than 6 months.

WARNINGS:

The reconstituted vaccine should be used within 6 hours at the latest.

* Vaccines exposed to high temperatures or sunlight, or 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.

* In rare cases of anaphylactic shock developing shortly after vaccination in susceptible animals, adrenergic and antihistaminic preparations should be administered.

* BRUDOLL-M Genç 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. Maladministration and eye and skin contamination should be avoided during reconstitution and vaccination. Asepsis and antisepsis principles should be followed during administration. Gloves should be used during vaccination, and an antiseptic solution should be available to be used when needed. The injection equipment should be decontaminated with appropriate disinfectants (phenolic, iodine or aldehydic) after vaccination. In case of an accidental contact, medical attention should be sought.

* As the vaccine may be dangerous for cattle, contact with cattle should be avoided.

WITHDRAWAL PERIODS:

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

STORAGE CONDITIONS:

Stored refrigerated at +2/+8°C and in the dark.

PRESENTATION:

25 doses of lyophilized vaccine with 25 ml solvent for reconstitution
50 doses of lyophilized vaccine with 50 ml solvent for reconstitution
100 doses of lyophilized vaccine with 100 ml solvent for reconstitution
200 doses of lyophilized vaccine with 200 ml solvent for reconstitution

SHELF LIFE:

24 months (2 years)

DISPOSAL PRECAUTIONS:

Unused or opened vials are disposed of as medical waste, according to the provisions of the applicable waste regulations.

LEAFLET APPROVAL DATE: 05.05.2009

DATE OF MARKETING AUTHORIZATION ISSUED BY MINISTRY OF AGRICULTURE AND FORESTRY: 05.05.2009

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:

Dollvet Biyoteknoloji Anonim Şirketi

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