



Brucevac[®] (full dose)

Lyophilisate for suspension for injection Live attenuated *Brucella melitensis* strain Rev.1 Vaccine

STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS:

- Active substance:
Each dose contains $0.5-2 \times 10^9$ CFU viable organisms of freeze-dried live attenuated *Brucella melitensis* strain Rev.1.
- Other ingredients
Trepone, sucrose and sodium glutamate.

INDICATIONS:

Brucevac (full dose) vaccine is used for the prevention of Brucellosis in sheep and goats.

CONTRAINDICATIONS:

Do not vaccinate sick or stressed animals.

ADVERSE REACTIONS:

Very rare: abortion is possible if given to pregnant animals during the last stage of pregnancy under stressful conditions.
If you notice any side effects please inform your veterinarian.

TARGET SPECIES:

Sheep and goats.

DOSAGE:

Vaccinate lambs and kids (only females) subcutaneously; (preferably in the elbow region) with a single dose (1ml) per animal at an age over 3 months and just before puberty.

ADVICE ON CORRECT ADMINISTRATION:

- Apply usual aseptic procedures.
- Use only clean, antiseptic or disinfectant-free materials for the preparation of the vaccine solution.
- Dissolve the freeze-dried pellet vaccine with the sterile solvent provided immediately before use.

- Use 10 ml solvent for 10 full doses vaccine vial, 25 ml solvent for 25 full doses vaccine vial and 50 ml solvent for 50 full doses vaccine vial.

WITHDRAWAL PERIOD:

- Meat: 21 days.
- Milk: 21 days.

SPECIAL STORAGE PRECAUTIONS:

- Store in a refrigerator (2°C-8°C).
- Protect from direct sunlight.
- Do not freeze.
- Keep out of the reach and sight of children.
- The vaccine remains stable for 18 months from production date stated on the label under the recommended storage conditions.
- Shelf life after reconstitution: Use the vaccine immediately after reconstitution (within two hours in cool conditions).

SPECIAL WARNING(S):

special warnings for each target species:

Vaccinate healthy animals only.

Special precautions for use in animals:
Not applicable.

Special precautions to be taken by the person administering the medicinal product to animals:

- *Brucella melitensis* Rev.1 vaccine is pathogenic for humans; care should be taken to avoid accidental injection.
- Medical advice should be sought in the event of accidental exposure.

Use during pregnancy, lactation, fertility:

Extra care should be taken when vaccinating lactating and breeding females.

Interaction with other medicinal products and other forms of interaction:

Do not use antibiotics or other antibacterial substances for 7 days before vaccination.

Overdose:

Rare: abortion is possible if given to pregnant animals during the last stage of pregnancy under stressful conditions.
If you notice any side effects please inform your veterinarian.

SPECIAL PRECAUTIONS FOR DISPOSAL:

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

OTHER INFORMATION:

Brucellosis is a serious bacterial zoonotic disease of sheep and goats. The disease is present in most countries of the world. It causes abortion, orchitis, arthritis, and inflammation of the accessory sex glands. The disease is best prevented and controlled by vaccination.

The vaccine has the following characteristics:

- Stable.
- Does not produce local or systemic reaction.
- Provides satisfactory protection for several years against *Brucella melitensis*.
- Vaccination is followed by a good immune response.

Package sizes:

Vials of: 10 doses, 25 doses and 50 doses.

FOR VETERINARY USE ONLY.

 Jovac

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