



# Bruce19vac<sup>®</sup>

## Lyophilisate for suspension for injection Live attenuated *Brucella abortus* strain S19 Vaccine

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

- Active substance:  
Each dose contains 50-100 x 10<sup>9</sup> CFU viable organisms of freeze-dried live attenuated *Brucella abortus* strain S19.
- Other ingredients  
Trepone, sucrose and sodium glutamate.

### INDICATIONS:

Bruce19vac vaccine is used for the prevention of *Brucellosis* in in cattle and buffaloes.

### 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:

Cattle and buffaloes.

### DOSAGE:

Vaccinate female calves (cattle & buffaloes) at age of 3-6 months with a single dose (3 ml) subcutaneously; (preferably under the skin of the neck just in front of the shoulders).

### 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 6 ml solvent for 2 doses vaccine vial, 15 ml solvent for 5 doses vaccine vial and 30 ml solvent for 10 doses vaccine vial.
- Use the vaccine immediately after reconstitution (within two hours in cool conditions).

### 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 abortus* S19 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 zoonotic disease and considered to be one of the most important diseases of animals caused by *Brucella* microorganisms.

### MANUFACTURING AUTHORIZATION HOLDER AND MANUFACTURED BY:

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Control measures are based on strict hygiene and vaccination of susceptible animals like cattle and buffaloes.

The vaccine has the following characteristics:

- Stable.
- Does not spread from animal to animal.
- Provides satisfactory protection for several years against *Brucella abortus*.
- Vaccination is followed by an immune responses and demonstration of specific antibodies.

### Package sizes:

Vials of: 2 doses, 5 doses and 10 doses.

### FOR VETERINARY USE ONLY.

**Jovac**