**Gudair Vaccine**

**Dosage form:** Vaccine.

**Composition:** Contains inactivated *Mycobacterium paratuberculosis* bacteria in an oil emulsion 250 mg/100 ml (m/v).

**Indications:** For the immunisation of sheep and goats as an aid in the control of paratuberculosis (Johne’s disease). It reduces the clinical signs due to the disease, as well as faecal shedding of the organisms. The use of this vaccine does not cure the disease.

**Note:**
- Johne’s disease is a controlled disease in terms of the Animal Diseases Act (Act 35/1984). The occurrence or suspicion of the disease thus has to be reported to the State Veterinary Services.
- The vaccine may only be purchased subject to a prescription obtained from a state veterinarian.
- The vaccine may only be used in infected herds under the direct supervision of a state veterinarian.
- Vaccinated sheep and goats have to be permanently identified to the satisfaction of the state veterinarian.

**Warnings:**
- Sheep and goats must not be slaughtered for human consumption within 42 days of vaccination.
- Keep out of reach of children, uninformed persons and animals.
- Accidental inoculation of humans with the vaccine may lead to an intense granulomatous reaction, not only at the site of injection, but also in other areas if the vaccine enters the bloodstream.
- As an immediate measure, wash area thoroughly with soap and water and apply a disinfectant, avoiding pressure or trauma on the area.
- Seek medical advice as soon as possible and produce this label. Inform the physician that the vaccine contains inactivated *Mycobacterium para-tuberculosis* bacteria in an oil-emulsion.
- As with other vaccines, hypersensitivity reactions may occur. Should this be the case, an antihistaminic therapy must be administered without delay.
- The vaccine produces a swelling at the injection site, which gradually becomes a persistent, fibrous and cold nodule, which takes 7-15 days to appear. In the case of vaccine inoculation of infected animals a more intense local reaction should be expected.
- Do not vaccinate wet animals and prevent animals getting wet after vaccination.
- Destroy any unused vaccine by, e.g. burning, and dispose of all the vaccine containers after use.
- Although this vaccine has been extensively tested under a wide variety of conditions, failure thereof may ensue as a result of a wide range of reasons. If this is suspected, seek veterinary advice and notify the registration holder.

**Precautions:**
- Use the entire contents of the bottle once opened.
- Do not mix the vaccine with other vaccines.
- Observe aseptic precautions. Ensure that all vaccination equipment is clean and sterile prior to use.
- It is good vaccination practice when handling the vaccine to avoid contact with the eyes, hands and clothing.

**Directions for use:** Use only as directed. Shake well before use. Administer 1 ml subcutaneously once only. In infected herds, the vaccination should be carried out on all individuals, including adult animals. Replacement animals should be vaccinated between 2 to 3 weeks and 6 months of age. Avoid administering in weight-bearing areas, and areas subjected to friction. Gudair should be injected high on the neck immediately behind the ear.

**Presentation:** 100 ml, 250 ml bottles.

**Storage instructions:** Store between 2-8 °C. Protect from light. Do not freeze.

**Registration number:** G3268 (Act 36/1947).