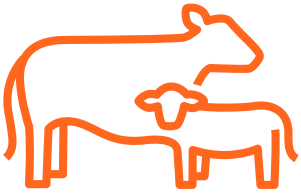
BEEF CATTLE PRODUCT INFORMATION SHEET



Silirum® Vaccine

Description

Silirum is Australia's only vaccine as an aid in the control of Bovine Johne's Disease (BJD). It contains inactivated (killed) *Mycobacterium avium* subsp. *paratuberculosis* strain 316F combined with an oil based adjuvant in a multiple emulsation for the active immunisation of cattle against *Mycobacterium avium* subsp. *Paratuberculosis.*

Key Benefits

- Provides industry with a very effective tool to complement on farm disease management practices relating to BJD and should be considered as a part of a general farm biosecurity plan to minimise the risk of BJD.
- Now registered in every state of Australia, with the exception of WA.
- Inactivated (killed) vaccine and will not introduce the disease into the flock.
- A single 1 mL dose provides lifelong immunity.

Approved Uses

Active immunisation of cattle against *Mycobacterium avium* subsp. *Paratuberculosis,* as an aid in the control of Bovine Johne's Disease (BJD or Paratuberculosis).

Dosage

- Shake well before use and keep thoroughly mixed during use.
- For subcutaneous use only.
- Inject subcutaneously high on the neck just behind the ear.
- The dose for cattle (3 weeks of age or older) is 1 mL.
- Further vaccine (booster) doses are not required.
- Administer with a Sekurus vaccinator only.
- Ensure that this vaccine does not enter your body (self- injection, needle scratch, etc.).
- As Silirum is a reactive substance, we recommend that you use a safely vaccinator that has a protective shroud.
- Unused vaccine may be stored and used for up to 30 days after first opening when stored in the original cardboard carton and place in the refrigerator (do not freeze). On each subsequent reuse, swab the opening with a suitable disinfectant (for example methylated spirits) both before and after using. See the label for further information on resealing. When not in use during any given vaccination session, keep the vaccine out of sunlight and as cool as possible. Do not leave exposed to light or at high temperatures for long. Ideally place the vaccine pack into its original cardboard carton and place in either a portable cooler with an ice brick or in a refrigerator. Contents should be left in outer package until immediately before use.

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Additional Information

This product can only be supplied on the authority of the State Chief Veterinary Officer or Chief Inspector of Stock or Director General of NSW Agriculture to approved people or their approved veterinarian, except in Victoria where the Chief Veterinary Officer grants a general approval for the use of Silirum vaccine.

This vaccine is not registered for use in Western Australia.

While vaccine should be used in herds where a diagnosis of BJD has been confirmed, consideration should also be given to vaccination of herds at risk of infection or for animals introduced into an infected herd. Consult your local veterinarian for the most effective control program in these circumstances.

Storage: Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light.

Withholding Period: Nil.

Schedule: Nil.

Caution: Avoid Carcass damage.

Sterilise all injection apparatus by boiling in water for 10 minutes (or equivalent) before use.
Avoid use of strong disinfectants on apparatus.

Maintain cleanliness at all times during vaccination. Great care must be taken to avoid contamination of the vaccine, needle and internal parts of the syringe by contact with unsterile surfaces or unwashed hands.

Keep needles sharp and clean. Replace frequently.

Use the shortest possible needle, certainly not exceeding 15 mm.

Avoid injection of animals during wet weather or under dusty conditions.

This product must be injected ONLY under the skin.

Packaging: Plastic pack: 20 mL and 50 mL.

Registered Label Warnings

Restraints

DO NOT vaccinate cattle intended for live export to countries requiring tuberculosis testing.

Cattle administered with this killed vaccine are likely to test positive for tuberculosis (caudal fold test) due to cross reactivity between the vaccine and the test.

DO NOT vaccinate cattle intended for live export to countries requiring JD negative antibody testing and/or certified JD-freedom property status.

Cattle administered with this killed vaccine may test positive when screened for Johne's Disease (JD-ELISA – blood antibody test) due to immunity developed to the vaccine.

All animals vaccinated with Silirum vaccine must be positively identified as Silirum vaccinated animals by a unique identifier. The preferred option for identification is the use of separate permanent ear tag (e.g,. NLIS style button) indicating JD vaccination status. In Victoria it is a legal requirement that cattle vaccinated with Silirum are permanently identified with a three hole ear punch.

Contraindications

Studies on the effects of vaccination on reproduction in male cattle have not been conducted.

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Precautions

Use of the vaccine must be considered in the context of other industry or government sponsored BJD management programs (e.g., CattleMAP). If you are currently managing cattle under one of these programs please consult your veterinarian, District Veterinary Officer or relevant industry representative prior to initiating a vaccination program in your herd.

Use of the vaccine may have potential effects on the cattle enterprise such as trading ability, CattleMAP status, false positive results to bTB and BJD testing etc.

Vaccinated cattle must be excluded from export markets that are sensitive to bovine Johne's disease or bovine tuberculosis unless there is an agreement on the eligibility for export of vaccinated animals with the importing country, Seek professional advice if you require further guidance.

Interaction

No information is available on the safety and efficacy of the concurrent use of this vaccine with any other products.

Side Effects

Vaccinated animals may experience an increase in body temperature for the first three days following vaccination. It is often normal for an injection site reaction to appear 7 – 15 days post vaccination, which in a small proportion of animals may become greater than 5 cm in diameter. At 3 months post vaccination most swellings have decreased in size, and continue to decrease over time, although a vaccination site nodule may persist for a prolonged period. When this vaccine is administered to animals already infected with, or sensitised to, *M. paratuberculosis,* a more intense local reaction (secondary immune response) may be observed.

User Safety Information

Ensure that the vaccine does not enter your body through contact with the needle (self-injection, needle scratch etc.) or entry through an open wound. Be especially careful that it does not enter your body through contact with eyes, mouth and skin, because the vaccine is an irritant. Wash hands thoroughly with soap and water after use, especially if the vaccine comes into contact with your skin. If the vaccine gets into the eyes, or mouth, immediately rinse the exposed area thoroughly with tap water and seek medical advice.

Take care to avoid accidental self-injection as this product contains mineral oil and is an irritant. It can cause pain and prolonged swelling (6 – 24 months) at the injection site and in the draining lymph nodes. Medical or surgical intervention may be required. In rare case it may result in the loss of a finger if injected into a finger joint or tendon sheath. In all instances of accidental self-injection, contact a doctor as soon as possible, even if only a very small amount is injected, and take the package insert and carton with you.

Allow the wound to bleed freely. Do not squeeze or interfere with the injection site. Clean the wound thoroughly with soap and water. Keep the wound clean and dry. If pain persists after medical examination, seek medical advice again.

First Aid

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

Further information on the treatment of accidental self-injection is available from the Poisons Information Centre 13 11 26 or Zoetis Veterinary Services 1800 814 883.

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