Information for healthcare professionals about human accidental or self-injection and exposure to the animal vaccines, GUDAIR® and SILIRUM®

What are GUDAIR and SILIRUM used for?

GUDAIR vaccine for sheep and goats and SILIRUM vaccine for cattle provide protection against an incurable and terminal wasting disease of livestock known as Johne's disease. Johne's disease is caused by the bacteria *Mycobacterium paratuberculosis*.

What is in GUDAIR and SILIRUM?

These vaccines contain:

- Inactivated *Mycobacterium paratuberculosis* organisms
- Mineral oil
- Thiomersal (preservative)

The oil-based vaccine typically forms a depot at the injection site, acting as a potent adjuvant in stimulating a cell-mediated immune response to the mycobacteria. The action of the adjuvant and antigen combination in this vaccine produces a reaction similar to that elicited by Freund's complete adjuvant.

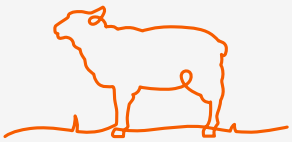
The potential consequences of accidental or self–injection with GUDAIR or SILIRUM

Even when a small amount of these vaccines is accidentally injected into a human, intense swelling and a persistent granulomatous inflammatory reaction can occur. If injected into a finger joint or tendon sheath, the product may track along the tendon. The swelling and inflammation post-injection may compromise blood supply and result in necrosis. In rare cases this can lead to the loss of a digit.

Common recommendations after suspected human exposure to GUDAIR or SILIRUM vaccine has occurred

After any human exposure or injection with GUDAIR or SILIRUM, the patient should immediately stop vaccinating and cease working until the severity of the exposure is properly assessed.

zoetis



Zoetis is aware that the following treatment strategies that have been recommended by doctors in the past:

1. **Superficial skin exposure, eye exposure and oral ingestion:**
   - **Skin contact:** wash the contaminated area with warm soapy water. If irritation develops and persists, or if the patient is concerned, seek medical attention.
   - **Eye splash:** remove contact lenses if worn and rinse eyes thoroughly with saline solution or, if not available, cool water from a running tap or a cup/jug. Continue to flush for at least 15 minutes and seek prompt medical attention.
   - **Oral ingestion:** rinse the mouth out with cool water. If irritation develops, the patient feels unwell or if they are concerned, seek medical attention.

2. **Needle-stick and needle scratch injuries without known injection of vaccine:**
   - Doctors have recommended that the wound be allowed to bleed freely and advised not to squeeze or interfere with the wound. Doctors have recommended that the wound then be cleaned thoroughly with warm water and then kept clean and dry.
   - Doctors have also considered that, following appropriate immediate local cleansing, corticosteroids may be indicated to decrease the severity of any local reaction. Antibiotics may also be indicated to treat secondary infections.
   - Doctors have determined the patient's tetanus immunisation status and administered a booster or primary series, as appropriate.
   - Commonly, if there is no pain or swelling 24 hours post-exposure, doctors have continued to monitor for at least a month and have treated any clinical symptoms that arise accordingly.

If pain and swelling is present after 24 hours, it should be considered that the vaccine has entered the body and the injury should be treated as described below:

3. **Suspected injection of vaccine:**
   - Doctors have observed that acute pain and inflammation is usually still evident 24 hours after the suspected injection occurred or after contamination of an open wound.
   - In cases of accidental self-injection (or needle stick or needle scratch, or contamination of an open wound) introducing vaccine into the body, surgical intervention may be required:
     — timing of surgery is at the discretion of the medical practitioner and surgeon
     — prior to surgery, medical management with systemic antibiotics and corticosteroids may be indicated
     — in the case of a lesion that has progressed to necrosis or granulomatous ulceration, perform surgical debridement to remove residual vaccine material
   - Surgeons have stated that meticulous technique has been required to stop inadvertent spread of the product during surgery.

Given the nature of this Freund's-like vaccine, Zoetis recommends that healthcare professionals speak with a surgeon who has experience with the treatment of cases of accidental or self-injection of GUDAIR or SILIRUM to ensure the appropriate treatment is advised.

If presented with a case of accidental or self–injection of GUDAIR or SILIRUM, healthcare professionals are advised to contact Zoetis on 1800 814 883.

If you would like further information, Zoetis can provide copies of the following published materials:

1. Murphy LA, Kode GM, Briffa J. Delayed debridement of Ovine Johne's disease vaccine (Gudair) inoculation: a case series. AJOPS. 2023;6(1):1-5. **2.** Fuzzard S, Richardson J, Liew J, Wiseman J, Teixerira R. Surgical management of Gudair sheep vaccine inoculation. *ANZ. J. Surgery.* 90(6): 1176-1178, October 2019. https://doi.org/10.1111/ans.15517. **3.** Windsor PA, Bush R, Links I and Eppleston G. Injury caused by self-inoculation with a vaccine of a Freund's complete adjuvant nature (Gudair TM) used for control of ovine paratuberculosis. Aust Vet J, 83:216-220, 2005. **4.** Richardson GD, Links II, Windsor PA. Gudair (OJD) vaccine self-inoculation: a case for early debridement. MJA, 183, 3, 1 August 2005. **5.** Jones DPG: Accidental self-inoculation with oil based veterinary vaccines. *NZ Med J,* 109:363-365, 1996. **6.** Patterson CJ et al.,: Accidental self-inoculation with Mycobacterium paratuberculosis bacteria by veterinarians in Wisconsin. JAVMA, 192, 9, 1197-9, 1988. **7.** Bjornsson A et al.,: Paratuberculosis of the hand: Case Report. Scand J Plast Reconstr Surg, 5: 156- 160, 1971.

Zoetis Australia Pty Ltd. ABN 94 156 476 425. Level 6, 5 Rider Boulevard, Rhodes NSW 2138. January 2025. ZL1886.