

Information for healthcare professionals about human accidental self-injection and exposure to Gudair[®] vaccine

What is Gudair vaccine used for?

Gudair vaccine is used in sheep and goats, to protect them from a wasting disease known as Johne's disease. Johne's disease is caused by *Mycobacterium paratuberculosis*.

What is contained in Gudair vaccine?

Each dose of Gudair vaccine contains:

- Killed *Mycobacterium paratuberculosis* organisms (heat inactivated)
- Mineral Oil
- Thiomersal (preservative)

The oil typically forms a depot at the injection site, to act 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.

Accidental self-injection

Gudair vaccine contains mineral oil. Even when a small amount 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. Every case is different and the correct medical advice is a matter for the treating physician.

Some common strategies recommended by healthcare professionals

We are aware of the following treatment strategies being frequently recommended by physicians in the past:

1. In the case of **superficial skin exposure, eye exposure and oral ingestion**:
 - **Skin contact**: doctors have recommended washing the contaminated area with warm soapy water.
 - **Eye splash**: doctors have recommended that any contact lens be removed and eyes be rinsed thoroughly with cool water from a running tap or a cup/jug and continue to flush for at least 15 minutes.
 - **Oral ingestion**: doctors have recommended the mouth be rinsed out with cool water.
2. In the case of **needle-stick injuries without known injection of vaccine**:
 - Doctors have recommended that the wound be allowed to bleed freely and that the wound or injection site not be squeezed or otherwise interfered with. 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 decrease the severity of any local reaction.
 - Doctors have frequently determined the patient's tetanus immunisation status and administered 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 treat any clinical symptoms accordingly. If pain and swelling persist after 24 hours, doctors have commonly considered that it is case of injection and treated the injury as described below.

3. In the case of **actual injection of Gudair vaccine:**

- Doctors have observed that acute pain and inflammation is usually still evident 24 hours after the suspected injection occurred.
- In some cases of self-injection, doctors consider that prompt surgical attention has been required and, in those case, the doctors have:
 - incised the wound to remove the vaccine, especially where there is involvement of finger pulp or tendon;
 - for chronic granulomatous reactions, complete curettage or total excision of the lesion has been performed;
 - In the case of a **lesion that has progressed to necrosis or granulomatous ulceration**, physicians have performed surgical debridement to remove residual vaccine material.

Doctors 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 any healthcare professional considering surgery speak with a surgeon who has experienced with the treatment of cases of self-injection to ensure the appropriate treatment is advised.

Relevant published information:

If you would like further information, we are happy to provide copies of the following published materials:

- 1) Richardson GD, Links II, Windsor PA. Gudair (OJD) vaccine self-inoculation: a case for early debridement MJA 183, 3, 1 August 2005
- 2) 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
- 3) Jones DPG: Accidental self-inoculation with oil based veterinary vaccines NZ Med J 109: 363 - 365, 1996
- 4) Patterson C J et al: Accidental self-inoculation with Mycobacterium paratuberculosis bacteria by veterinarians in Wisconsin. JAVMA, 192, 9, 1197-9, 1988
- 5) Bjornsson A et al: Paratuberculosis of the hand: Case Report. Scand J Plast Reconstr Surg 5: 156-160, 1971

Zoetis' contact details

Any healthcare professional that has any questions about the Gudair vaccine should call Zoetis on 1800 814 883.