

**READ SAFETY DIRECTIONS  
FOR ANIMAL TREATMENT ONLY**

# Gudair®

Vaccine

This vaccine contains a suspension of the microorganism, *Mycobacterium paratuberculosis*, strain 318F, inactivated by heat and adjuvanted with mineral oil in a multiple emulsion. It contains 2.5 mg of dried microorganisms per mL. This must be used as preservative.

Active immunisation for the control of Johne's Disease and reduction in faecal *Mycobacterium paratuberculosis* shedding in sheep. Active immunisation as an aid in the control of Johne's Disease in goats.

#### INDICATIONS FOR USE

Gudair® Vaccine is indicated for the control of Johne's Disease in sheep and as an aid in the control of Johne's Disease in goats.

In a infection of *Mycobacterium paratuberculosis* in sheep and goats is primarily by the faecal-oral route. The bacteria enter through the Peyer's patches of the small intestine and infect the terminal ileum, caecum, colon and associated mesenteric lymph nodes and vessels. Johne's disease has a prolonged incubation period with clinical disease characterised by weight loss and emaciation, most commonly seen in sheep older than two years of age. About 10% of clinical cases show diarrhoea in the end stages of the disease. Some animals become carriers of the infection, intermittently shedding the bacteria into their environment. These subclinical carriers can develop into active clinical cases which usually die from malabsorption. Milk production in infected sheep and goats is reduced and wool break and poor fleece condition have been reported in infected sheep.

In infected or at risk flocks, vaccination can be carried out on all of the flock, including adult animals. Following whole flock vaccination, a significant decrease in the number of clinically affected animals may not be observed for several months, but the number of mortalities may decrease substantially. There will then be a gradual decrease in the prevalence of infection within the flock, with a notable decrease in faecal *M. paratuberculosis* shedding. It is recommended that all replacement animals be vaccinated at a young age. When vaccination is commenced at between 1 and 4 months of age, faecal *M. paratuberculosis* shedding may be prevented for 12 months or longer post-vaccination.

#### DIRECTIONS FOR USE

Use of this vaccine may be restricted in your State or Territory. Contact your local Department of Agriculture for similar) for details.

#### Dosage and Administration

Shake well before use and keep thoroughly mixed during use.

Use all product within 12 hours of opening.

Inject the vaccine subcutaneously high on the neck just behind the ear. Do

not inject at any other site. The dose for sheep and goats (greater than 11 months of age) is 1 mL. Further vaccine ( booster) doses are not required.

Ensure sheep are adequately restrained during the injection process and take care to avoid accidental self-injection. It is recommended that you use the Pfizer Secure 1 mL vacuolator, available from your distributor, when using this vaccine.

**NOTE: SHEEP AND GOATS TREATED WITH THIS VACCINE ARE LIKELY TO GIVE POSITIVE RESULTS WHEN TESTED FOR TUBERCULOSIS OR JOHNE'S DISEASE.**

#### CAUTION AVOID CARCASS DAMAGE

1. Sterilise all injection apparatus by boiling in water for 10 minutes for repeated before use. Avoid use of airway disinfectants on apparatus.
2. 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 unclean hands.
3. Keep needles sharp and clean. Replace frequently.
4. Use the shortest possible needle, certainly not exceeding 15 mm.
5. Avoid injection of a animal during wet weather or under dusty conditions.
6. This product must be injected only under the skin.
7. Inject high on the neck just behind the ear. Do not inject at any other site. Young lambs may be vaccinated while being restrained in a lamb cradle.

#### SIDE EFFECTS

After vaccination a firm swelling usually develops at the site of injection. At 2 months post-vaccination most swellings have decreased in size, and continue to decrease over time. It is often normal for an injection site nodule to appear 7-15 days post-vaccination, which in a small proportion of animals may become greater than 5 cm in diameter. 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.

In a small proportion (5%) of animals the swelling may develop into an abscess and burst. This may attract flies and vaccinated animals should be checked regularly for fly strike and be treated where necessary or preventatively. Fly strike treatment should be given. Vaccinated animals, if used for slaughter soon after vaccination, may be subject to additional tanning due to vaccination injection site reactions. Attention to good vaccination technique and administering the vaccine just behind the ear should minimise the risk of this occurrence.

#### WITHHOLDING PERIODS (MEAT, MILK) NIL

#### USER SAFETY INFORMATION

Avoid contact with eyes, mouth and skin, as the vaccine is irritant. Wash hands thoroughly after use with soap and water, especially if the vaccine contacts the skin. If the vaccine gets into the eyes or mouth rinse the exposed area thoroughly with tap water.

Take care to avoid accidental self-injection as this product contains mineral oil and is very irritant. It can cause pain and a prolonged swelling (8-24 months) at the injection site and in the draining lymph nodes. Medical or surgical intervention may be required. In rare cases 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 this package insert and carton with you.

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38-42 Warrat Road West Ryde NSW 2114 AUSTRALIA

Allow the wound to bleed freely and do not squeeze or interfere with the injection site to avoid a spread of the vaccine. Clean the wound thoroughly with soap and water, and then keep it clean and dry. If pain persists after medical examination, seek medical advice again.

#### INFORMATION FOR THE MEDICAL PRACTITIONER

This product contains mineral oil. Even if small amounts of this product have been accidentally injected, it can cause intense swelling and a persistent granulomatous inflammatory reaction. If injected into a finger joint or tendon sheath, the product may track along the tendon. The swelling and inflammation may compromise blood supply and result in necrosis that, in rare cases, may lead to the loss of a digit.

Following appropriate immediate local cleansing, it has been suggested that corticosteroids may decrease the severity of any local reaction. Ascertain the patient's tetanus immunization status, and provide booster or primary doses, as appropriate.

In cases of accidental self-injection **PROVISE** surgical attention is required. The wound should be incised and irrigated to remove the vaccine, especially where there is involvement of finger pulp or tendon. Complete curettage or total excision of the lesion is required for chronic granulomatous reactions. Meticulous technique is required to stop further spread of the product.

Accidental self-injection of this vaccine may result in cross-reaction with, and a false positive test result for, human tuberculosis.

Further information on treatment is available from Pfizer Information Centre, Phone Australia 13 11 24, New Zealand 0800 POSION (0800 744 766) or Pfizer Animal Health Australian Technical Services Toll Free on 1800 814 883, New Zealand Technical Services Toll Free on 0800 650 277.

#### MODE OF ISSUE

Gardyl<sup>®</sup> Vaccine is issued in packs of 100 mL and 250 mL.

#### STORAGE

Store between 2°C and 8°C (refrigerate. Do not freeze). Protect from light.

#### DISPOSAL

Dispose of empty containers by putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled 'sharps' container.

#### NOTE

This vaccine has been fully tested for stability and safety before issue, but it must be stressed that correct vaccination procedure in the field is equally important if secondary infection is to be prevented. Very occasionally, pathogenic organisms lying dormant in the animal's tissues are activated at the time of vaccination. This may lead to losses of stock, but fortunately is of rare occurrence. As the above factors are beyond the control of the manufacturer except to the extent of any liability imposed by statute law without right of exclusion, Pfizer cannot accept responsibility for any disability or loss of stock following vaccination in respect of failure to use the correct vaccination procedure described on the label or disability or loss to any animal caused by the product.

Australian Technical Services Toll Free 1800 814 883  
[www.pfizeranimalhealth.com.au](http://www.pfizeranimalhealth.com.au)  
APVMA 5383900025

#### NEW ZEALAND INFORMATION BOX

In New Zealand, it is a legal requirement that this product is used only in sheep and goats.

#### COMPULSORY EARMARKING

All vaccinated animals are to be permanently identified by the Ministry of Agriculture and Forestry (MAF) approved 'Colour's Vaccination Earmark'. The earmark is to be placed in either ear as a stamp in a fore-lip or back-lip position depending on which position leaves the clearest possible identifying mark. The mark should not be an earmark placed in a punch hole, tip or quarter. The earmark must be made at the time of vaccination. Earmarking pliers are available from your veterinarian.



#### Prescription Animal Remedy (PAR) Class 1

For use only under the authority or prescription of a veterinarian.

Registered pursuant to the ACVM Act 1987 No. A2996

See [www.maf.govt.nz/acvm](http://www.maf.govt.nz/acvm) for registration conditions.

Registered to Pfizer New Zealand Limited

14 Hornsby Road, Mt Eden, Auckland

NZ Technical Services Toll Free 0800 650 277

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August 2005