

GUDAIR[®] VACCINE- USER SAFETY INFORMATION

Please read all of this information carefully. Keep it in a safe place, as you may want to read it again, or show it to your doctor.

What is Gudair[®] Vaccine for?

Gudair[®] Vaccine is used in sheep and goats, to protect them from a wasting disease known as Ovine Johne's Disease.

Who needs to be careful?

All people who handle Gudair[®] vaccine; in particular, people who:

- Prepare the injection
- Handle the injection equipment, before and after use.
- Inject animals

What is in Gudair[®] vaccine?

Each dose of Gudair[®] vaccine contains:

- Killed *Mycobacterium paratuberculosis* bacteria
- Paraffin Oil
- Thiomersal preservative

Why do I need to be careful?

Gudair[®] vaccine is harmful if it is accidentally injected into humans, because it has been made specifically:

- For use in animals and
- To produce a prolonged and strong immunity in those animals.

It is therefore important that you handle Gudair[®] vaccine very carefully, and

- Avoid accidental self-injection
- Do not get Gudair[®] vaccine on your skin (especially broken skin), in your eyes, or in your mouth.

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 (6-24 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.

How can I prevent accidental exposure?

Do not allow Gudair[®] vaccine to come into contact with:

- Any skin surface
- The lips, or the inside of the mouth
- The eyes

Wash hands thoroughly after use with soap and water, especially if the vaccine contacts the skin.

Avoid accidental self-injection, For example:

- Ensure proper animal restraint when vaccinating.
- Ensure the vaccinators are appropriately controlled and not allowed to hang freely when handling sheep.
- Remove needles with pliers.
- Dispose of needles in an appropriate container

THINGS YOU MUST DO IF GUDAIR[®] VACCINE GETS ON YOUR SKIN:

If your skin is unbroken:

- Wash the area thoroughly with soap and water.

If your skin is broken:

- Wash the area thoroughly with soap and water.
- Apply a disinfectant solution, recommended for humans.

If you have a superficial needle- scratch:

- Treat as for broken skin.

If the area of skin becomes inflamed:

- **See a doctor** and take the package insert and carton with you.

THINGS YOU MUST DO IF GUDAIR[®] VACCINE GETS INTO YOUR EYES OR MOUTH.

- Rinse the exposed area thoroughly with tap water.
- **See a doctor and take the package insert and carton with you if irritation or discomfort persists.**

THINGS YOU MUST DO IF YOU ACCIDENTALLY SELF-INJECT GUDAIR[®] VACCINE

- **In all instances of accidental self-injection contact and see 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.
- Check your tetanus immunisation status and if necessary, have Tetanus shot(s).

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

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I have read and understood the Gudair[®] Vaccine – User Safety Information

Name:

Signature

Date:

Data Entry Number: