Q-VAX®

Q fever Vaccine

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about Q-VAX®. It does not contain all the available information. It does not take the place of talking to your doctor or other health professional.

Keep this leaflet.
You may want to read it again.

All medicines, including vaccines, have risks and benefits. Your doctor considers the risks of you having QVAX® and the benefits they expect it will have for you.

If you have any concerns about this vaccine, ask your doctor or other health professional.

What Q-VAX® is used for

Q-VAX® Q fever Vaccine is given by injection under the skin, usually in the upper arm. It is used to help protect people against the infection "Q fever."

Q fever is caused by bacteria (called *Coxiella burnetii*) which can be caught by humans from animals that carry the infection. These bacteria can cause illness in humans, sometimes mild, sometimes severe.

Vaccination with Q-VAX® is recommended for people working with cattle, sheep or goats, or products from these animals, for example

- abattoir workers, and visitors
- veterinary personnel
- stockyard workers
- farmers
- shearers
- animal transporters
- laboratory workers handling potentially infected veterinary samples or visiting abattoirs
- people who cull and process kangaroos.

The risk of becoming infected with Q fever is highest in the first few years of exposure. Workers who are at risk of contracting Q fever should be immunised as soon as possible after they commence work.

How Q-VAX® works

Q-VAX® works by causing your body to produce its own protection against the *Coxiella burnetii* bacteria that cause Q fever. After you are vaccinated with Q-VAX® your immune system is able to destroy the Q fever organism if you come into contact with it. This prevents you from getting Q fever. However, your body does take several weeks after vaccination to fully develop this protection against Q fever.

Protection by vaccination requires one dose of Q-VAX® Vaccine. Protection lasts for many years.

You must not be given Q-VAX® Vaccine more than once.

As with all vaccines, 100% protection cannot be guaranteed.

However, most people will be protected against Q fever.

The risk of having a severe unwanted reaction from Q-VAX® is small. The risks from NOT being vaccinated against Q fever may be serious.

Before you are given Q-VAX ®

Before you are given Q-VAX® Vaccine, your doctor will give you a skin test and a blood test to check if you are already immune to Q fever

When you must NOT be given Q-VAX® Vaccine

Do not have Q-Vax® Vaccine if:

- you have previously been vaccinated with Q-VAX ®
- you have had Q fever
- you have been exposed to the bacteria and you have had a Q fever-like illness
- you have not had the required Q Fever skin test AND blood test.
- the skin test OR the blood test show your doctor that you already have immunity against Q fever.

Note: Do not have Q-VAX® Vaccine unless both your skin test AND blood test are negative.

Tests required before having Q-VAX®

- **skin test**

and

- **blood test.**

The Q-VAX ® Skin Test is a small injection (0.1mL) in your forearm. The forearm must then be checked by your health professional seven days after the test injection. If the skin test is positive, a small lump will be present.

For the blood test, your blood sample is examined in a specialised laboratory. The test results are sent to your doctor.

Positive skin and/or blood tests show that you are already protected against Q fever. (The illness Q fever may be mild and difficult to diagnose. You may have had Q fever without realising it.)

If either or both of the skin and blood tests are positive, it is important that you DO NOT HAVE THE Q-VAX®VACCINATION. If you are already immune to Q fever, Q-VAX® vaccination may cause a severe reaction.

Do not have Q-VAX® if you have or previously had an allergy to:

- eggs
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives.

Q-VAX® is not recommended for use in children.

There is no information on the use of Q-VAX® in people who have poor immunity or are on treatment that lowers immunity.

Do not have Q-VAX® after the expiry date (EXPIRY) printed on the pack.

Do not have Q-VAX® if the packaging is torn or shows signs of tampering.

If you are not sure whether you should have Q-VAX®, talk to your doctor.

Before you are given Q-VAX ®

Tell your doctor if you have ever reacted to any vaccination with any of the following:

- severe allergic reaction
- difficulty breathing
- swelling of the throat
- fainting or collapse
- fits or convulsions
- high temperature (greater than 38.5 degrees C)
- severe skin reaction at the injection site, including severe bruising.

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you have worked with farm animals or been in contact with animal carcasses.

Tell your doctor if you are pregnant or intend to become pregnant.
There is no information on the use of Q-VAX® in pregnancy. It is recommended that vaccination is deferred. Your doctor will discuss the possible risks and benefits with you.

Tell your doctor if you are breastfeeding.
There is no information on the use of Q-VAX® during breastfeeding.

Your doctor will discuss the possible risks and benefits of having Q-VAX®.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

How Q-VAX® is given

Remember: you should not be given Q-VAX® Vaccine unless your skin test and blood test are both negative.

Q-VAX ® vaccination is given by injection by a trained health professional. It is injected just underneath the skin, usually in your upper arm.

How much is given

Q-VAX® Vaccine is pre-filled in a single-use syringe. This contains one 0.5mL dose.

Overdose is unlikely as your doctor gives you the vaccination.

One vaccination only is given.

You should NOT be given a booster dose of Q-VAX® Vaccine.

A second dose may cause a severe reaction.

Follow the advice (see below) about keeping a record of this vaccination.

If you have any concerns, ask your doctor.

After having Q-VAX ®

Things you must do

You must be given Q-VAX ® by a trained health professional, where there are facilities to manage any allergic reaction.

Allergy to Q-VAX® is uncommon, but allergy to any vaccine may occur.

Keep an updated record of all your vaccinations.

Ask the doctor to give you a written record of the injection stating the date, dose and batch number of the vaccine.

If you develop any medical problems after being given Q-VAX®, tell your doctor.

Q-VAX® is unlikely to affect your ability to drive or operate machinery.

Side effects

Tell your doctor as soon as possible if you do not feel well after receiving Q-VAX®.

All medicines, including vaccines, can have side effects. Q-VAX® vaccination may cause unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- reactions around the injection site such as redness, itchiness, pain or discomfort, warmth, burning or stinging, swelling or the formation of hard lumps or scars (up to 6 months after vaccination)
- headaches
- fever
- aching muscles
- fatigue
- generally feeling unwell
- nausea
- vomiting
- diarrhoea
- increased sweating

These side effects are usually mild.

Serious side effects are rare.

Tell your doctor immediately if you notice any of the following:

- infection or an abscess at the injection site
- painful, swollen joints
- sudden extreme tiredness or weakness.
- swollen glands
- feeling faint.

These may be serious side effects. You may need urgent medical attention.

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

Do not be unduly alarmed by the list of possible side effects.
You may not experience any of them.

Storing Q-VAX ®

Q-VAX® is usually stored in the doctors surgery or clinic. However, if you need to store Q-VAX®:

- **Keep it where children cannot reach it**
- **Keep Q-VAX® in the original pack until it is time for it to be given**
- **Keep it in the refrigerator between 2 degrees C and 8 degrees C and protect it from light. Do not freeze Q-VAX®.**

Product description

What it looks like

- Q-VAX® Q fever Vaccine is supplied in a pre-filled glass syringe containing 0.5mL of a slightly cloudy colourless liquid.

Each Q-Vax® Vaccine syringe is in a clear film wrapper.

Do not use if the film wrap is damaged or missing.

- Q-VAX® Skin Test is supplied in a glass vial containing 0.5mL of a clear colourless liquid.

The Q-Vax® Skin Test vial has a removable plastic cap covering the top of the vial. Do not use if the removable plastic cap is damaged or missing.

Ingredients

Active ingredient:

Q-VAX® Q fever Vaccine

- Each 0.5mL dose of vaccine contains no less than 25 micrograms of killed *Coxiella burnetii* organisms.

Q-VAX® Skin Test

- Each diluted 0.1mL dose contains 16.7 nanograms of killed *Coxiella burnetii* organisms.

Other ingredients:

- sodium chloride
- sodium phosphate monobasic
- sodium phosphate dibasic
- thiomersal.

Q-VAX® may also contain traces of

- formalin
- egg proteins
- sucrose.

Q-VAX® does NOT contain:

- lactose
- gluten
- tartrazine or
- any other azo dyes.

Ask your doctor or other health professional if you are unsure about anything or want more information about Q-VAX®.

Name and Address of Sponsor

Q-VAX® is sponsored by:

Seqirus Pty Ltd
ABN 26 160 735 035
63 Poplar Road, Parkville
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AUSTRALIA

Registration numbers

Q-VAX ® Q fever Vaccine
AUST R 100517

Q-VAX® Skin Test
AUST R 100518

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