

# Q-VAX<sup>®</sup> Q Fever Vaccine and Skin Test

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Q-VAX<sup>®</sup>?

Q-VAX<sup>®</sup> Q Fever Vaccine and Skin Test contain the active ingredient Inactivated *Coxiella burnetii*. Q-VAX<sup>®</sup> Vaccine is used to help protect people against the infection "Q fever." Q-VAX<sup>®</sup> Skin Test is given 7 days before Q-VAX<sup>®</sup> Vaccine to check if you have sensitisation (immunity) to Q fever.

For more information, see Section [1. Why am I using Q-VAX<sup>®</sup>?](#) in the full CMI.

### 2. What should I know before being given Q-VAX<sup>®</sup>?

Do not use if:

- You have been previously vaccinated with a Q fever vaccine.
- You have had Q fever infection in the past.
- You have been previously exposed to the bacteria and have had a Q fever-like illness
- The Skin Test OR the blood test performed 7 days before being given Q-VAX<sup>®</sup> Vaccine show your doctor that you already have immunity against Q-fever.
- You have ever had an allergic reaction to eggs or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before being given Q-VAX<sup>®</sup>?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Q-VAX<sup>®</sup> and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How is Q-VAX<sup>®</sup> given?

- The dose of Q-VAX<sup>®</sup> Vaccine is 0.5 mL injected under the skin.
- Remember: you should not be given Q-VAX<sup>®</sup> Vaccine unless your skin test and blood test are both negative.

The Q-VAX<sup>®</sup> 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 skin test injection. More instructions can be found in Section [4. How Q-VAX<sup>®</sup> is given](#) in the full CMI.

### 5. What should I know while being given Q-VAX<sup>®</sup>?

|                             |                                                                                                                                                                                     |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Things you should do</b> | <ul style="list-style-type: none"><li>• Tell your doctor if you are pregnant or intend to become pregnant.</li><li>• Tell your doctor if you experience any side effects.</li></ul> |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

For more information, see Section [5. What should I know while being given Q-VAX<sup>®</sup>?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects may include redness, pain, warmth and swelling at the injection site, delayed reactions at the injection site (occurring up to 6 months later) and headache. These side effects are usually mild. Serious side effects are rare.

Appropriate medical treatment and supervision should always be available during the injection in case of allergic reaction. If you experience this, tell your doctor immediately. Typical symptoms include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Q-VAX<sup>®</sup> Q Fever Vaccine and Skin Test

Active ingredient(s): Inactivated *Coxiella burnetii*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Q-VAX<sup>®</sup>. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Q-VAX<sup>®</sup>.**

Where to find information in this leaflet:

- [1. Why am I using Q-VAX<sup>®</sup>?](#)
- [2. What should I know before I use Q-VAX<sup>®</sup>?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Q-VAX<sup>®</sup> given?](#)
- [5. What should I know while being given Q-VAX<sup>®</sup>?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using Q-VAX<sup>®</sup>?

Q-VAX<sup>®</sup> Q fever Vaccine and Skin Test contain the active ingredient Inactivated *Coxiella burnetii*.

Q-VAX<sup>®</sup> Vaccine is used to help protect people against Q fever infection.

Q-VAX<sup>®</sup> Vaccine works by causing your body to produce its own protection against the *Coxiella burnetii* bacteria that causes Q fever.].

Q-VAX<sup>®</sup> skin test is required 7 days before having Q-VAX<sup>®</sup> Vaccine to check if you have sensitisation (immunity) to Q fever.

### 2. What should I know before being given Q-VAX<sup>®</sup>?

#### Warnings

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

**Q-VAX<sup>®</sup> should not be given if:**

- You are allergic to eggs or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- You have been previously vaccinated with a Q fever vaccine.
- You have had Q fever infection in the past.
- You have been previously exposed to the bacteria and have had a Q fever-like illness

- The Skin Test OR the blood test performed 7 days before being given Q-VAX<sup>®</sup> Vaccine show your doctor that you already have sensitisation (immunity) against Q fever.

**Check with your doctor if you:**

- have any other medical conditions
- take any medicines for any other condition

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

Q-VAX is not recommended for use in children.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

### 3. What if I am taking other medicines?

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

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Q-VAX<sup>®</sup> Vaccine.**

### 4. How is Q-VAX<sup>®</sup> given

#### How much is given

- The dose of Q-VAX<sup>®</sup> Vaccine is 0.5 mL injected under the skin.
- Do not have Q-VAX<sup>®</sup> Vaccine unless both your skin test AND blood test are negative.**
- The Q-VAX<sup>®</sup> 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 skin test injection. If the skin test is positive, a small lump will be present.

## 5. What should I know while being given Q-VAX®?

### Things you should do

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

### Things you should not do

- You should NOT be given a booster dose of Q-VAX® Vaccine.
- A second dose may cause a severe reaction.
- Follow the advice (see above) about keeping a record of this vaccination.
- If you have any concerns, ask your doctor.

### Looking after your medicine

Q-VAX® is usually stored in the doctor's 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®.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

| Less serious side effects                                                                                                                                                                                                                                                                                                                                                                                                                         | What to do                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>• 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)</li><li>• headaches</li><li>• fever</li><li>• aching muscles</li><li>• fatigue</li><li>• generally feeling unwell</li><li>• chills</li><li>• nausea</li><li>• vomiting</li><li>• diarrhoea</li></ul> | <b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b> |

|                                                                       |  |
|-----------------------------------------------------------------------|--|
| <ul style="list-style-type: none"><li>• increased sweating.</li></ul> |  |
|-----------------------------------------------------------------------|--|

### Serious side effects

| Serious side effects                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | What to do                                                                                                                                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>• infection or an abscess at the injection site</li><li>• painful, swollen joints</li><li>• sudden extreme tiredness or weakness</li><li>• swollen glands</li><li>• feeling faint.</li></ul> <p><b>Appropriate medical treatment and supervision should always be available during the injection in case of allergic reaction. Sudden signs of allergy include:</b></p> <ul style="list-style-type: none"><li>• Rash</li><li>• Itching or hives on the skin</li><li>• Swelling of the face, lips, tongue or other parts of the body,</li><li>• Shortness of breath, wheezing or trouble breathing.</li></ul> | <b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b> |

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Q-VAX® contains

|                                                 |                                                                                                                  |
|-------------------------------------------------|------------------------------------------------------------------------------------------------------------------|
| <b>Active ingredient (main ingredient)</b>      | Inactivated <i>Coxiella burnetii</i>                                                                             |
| <b>Other ingredients (inactive ingredients)</b> | <ul style="list-style-type: none"><li>• sodium chloride</li><li>• monobasic sodium phosphate dihydrate</li></ul> |

|                            |                                                                                                                                                                                                                                                                                                  |
|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                            | <ul style="list-style-type: none"> <li>• dibasic sodium phosphate dodecahydrate</li> <li>• thiomersal (as preservative)</li> <li>• water for injections</li> </ul> <p>Q-VAX® may also contain traces of</p> <ul style="list-style-type: none"> <li>• formalin</li> <li>• egg proteins</li> </ul> |
| <b>Potential allergens</b> | <ul style="list-style-type: none"> <li>• Egg</li> </ul> <p>The vial and all associated components do not contain natural rubber latex.</p>                                                                                                                                                       |

**Do not take this medicine if you are allergic to any of these ingredients.**

### **What Q-VAX® looks like**

Q-VAX® Vaccine is a clear to slightly opaque, colourless suspension in a pre-filled syringe (AUST R 100517) or a pre-filled vial (AUST R 523123).

Q-VAX® Skin test is a clear to slightly opaque, colourless suspension for dilution in a pre-filled vial. (AUST R 100518)

### **Who distributes Q-VAX®**

Seqirus Pty Ltd, ABN 26 160 735 035  
63 Poplar Road  
Parkville 3052  
Victoria  
Australia

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