

# Flucelvax<sup>®</sup> Quad

## 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, nurse or pharmacist.

### 1. Why am I being given Flucelvax<sup>®</sup> Quad?

Flucelvax<sup>®</sup> Quad Quadrivalent Influenza Vaccine (surface antigen, inactivated, prepared in cell cultures) contains the active ingredient influenza virus haemagglutinin. Flucelvax<sup>®</sup> Quad is used to help prevent certain types of influenza or “flu”.

For more information, see Section [1. Why am I being given Flucelvax<sup>®</sup> Quad?](#) in the full CMI.

### 2. What should I know before being given Flucelvax<sup>®</sup> Quad?

Tell your doctor, nurse or pharmacist if you or your child have ever had a severe allergic reaction to any influenza vaccine or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you or your child 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 Flucelvax<sup>®</sup> Quad?](#) in the full CMI.

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

Some medicines may interfere with Flucelvax<sup>®</sup> Quad 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 Flucelvax<sup>®</sup> Quad given?

- Flucelvax<sup>®</sup> Quad is given as an injection, usually into your upper arm muscle by a doctor, nurse or pharmacist.
- Flucelvax<sup>®</sup> Quad is given once every year, as follows:
  - Adults and children 9 years and older: one injection of 0.5 mL.
  - Children 6 months to less than 9 years of age: One or two 0.5 mL doses. Children less than 9 years of age who have not been previously vaccinated against influenza, should receive a second dose (at least 4 weeks after the first dose). In young children, it may be given in the thigh muscle of the leg.

More instructions can be found in Section [4. How is Flucelvax<sup>®</sup> Quad given?](#) in the full CMI.

### 5. What should I know about being given Flucelvax<sup>®</sup> Quad?

<b>Things you should do</b>	Call your doctor straight away if you or your child do not feel well after having Flucelvax <sup>®</sup> Quad. Keep an updated record of you and your child’s vaccinations. Keep any follow-up appointments with your doctor or clinic.
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For more information, see Section [5. What should I know about being given Flucelvax<sup>®</sup> Quad?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects may include local reaction around injection site, headache, tiredness, muscle ache and nausea. Mostly these are mild and short lived. Serious side effects are rare.

Sudden signs of allergy may be a serious side effect. If you or your child 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 or your child have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Flucelvax<sup>®</sup> Quad

Active ingredient(s): *influenza virus haemagglutinin*

## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**

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

## 1. Why am I being given Flucelvax<sup>®</sup> Quad?

**Flucelvax<sup>®</sup> Quad contains the active ingredient influenza virus haemagglutinin.**

Flucelvax<sup>®</sup> Quad is used to help prevent certain types of influenza or “flu”. It is for use in people 6 months of age and older.

Flucelvax<sup>®</sup> Quad works by causing your body to produce its own protection against the four types of influenza virus from which it is made. It does this by making substances called antibodies in the blood that fight the influenza virus. If a vaccinated person comes into contact with the influenza virus, the body is usually ready to destroy it.

Your body usually takes 2 – 3 weeks after vaccination to develop protection against influenza.

As influenza viruses can change from year to year, Flucelvax<sup>®</sup> Quad may be changed to contain fragments of the new types of virus. Therefore, yearly vaccination is recommended.

Please note that an influenza vaccine may only protect you against the types of influenza virus from which it is made. It will not protect you from other types of influenza virus or from infections with other agents causing flu-like symptoms (such as the common cold).

Most people will produce enough antibodies against the influenza virus. However, as with all vaccines, 100% protection cannot be guaranteed.

The virus in the vaccine has been killed. Therefore, the vaccine cannot give you or your child “the flu”.

## 2. What should I know before being given Flucelvax<sup>®</sup> Quad?

### Warnings

**Flucelvax<sup>®</sup> Quad should not be given if:**

- you or your child have been severely allergic to any previous influenza vaccine, or are allergic to any of the ingredients listed at the end of this leaflet.
- symptoms of a severe 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.
- a minor illness such as a cold should not be a problem but talk to your doctor if you have a high temperature or sudden illness.
- Flucelvax<sup>®</sup> Quad is not recommended for use in persons under 6 months.

**Tell your doctor if you or your child:**

- have any other medical conditions especially the following:
  - Guillain-Barre Syndrome (an inflammatory illness affecting the nerves resulting in weakness of muscles),
  - lowered immunity due to diseases such as some blood disorders, malaria, kidney disease requiring dialysis, HIV/AIDS or cancer,
  - lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy),
- have reacted to previous vaccination with severe allergic reaction (anaphylaxis), shortness of breath or trouble breathing, swelling of the throat, fainting or collapse, shock-like state or being unresponsive for a long time, fits or convulsions, temperature (greater than 38°C), severe skin reaction at the injection site, including severe bruising,
- take any medicines for any other condition,
- have allergies to any other substances such as latex, foods, preservatives or dyes.

After vaccination, you or your child 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.

Your doctor will discuss the potential risks and benefits of being given Flucelvax® Quad with regards to pregnancy or while you are breast-feeding.

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

Tell your doctor, nurse or pharmacist if you or your child 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.

**Some medicines may interfere with Flucelvax® Quad and affect how it works.**

e.g.

- Immunoglobulins, blood products used to prevent some infections,
- Medicines which lower the immune system, such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy).

Your doctor will consider whether an adjustment of medication is necessary.

Tell your doctor if you or your child have had any vaccines in the last 4 weeks.

**Check with your doctor, nurse or pharmacist if you are not sure about what medicines, vitamins or supplements you or your child are taking and if these affect Flucelvax® Quad.**

### 4. How is Flucelvax® Quad given?

#### How much is given

- Flucelvax® Quad is given once every year, as follows:
  - Adults and children 9 years and over: one injection of 0.5 mL
- Children 6 months to less than 9 years of age: One or two 0.5 mL doses. Children less than 9 years of age who have not been previously vaccinated against influenza, should receive a second dose (at least 4 weeks after the first dose).

#### When is Flucelvax® Quad given

- Flucelvax® Quad is usually given before the start of the influenza season or when recommended by your doctor, nurse or pharmacist.
- Vaccination for influenza should be repeated every year as new types of influenza virus can appear each year.

#### How is Flucelvax® Quad given

- Flucelvax® Quad is given as an injection, usually into your upper arm muscle by a doctor, nurse or pharmacist.
- In young children, it may be given in the thigh muscle of the leg.

### 5. What should I know about being given Flucelvax® Quad?

#### Things you should do

- Call your doctor straight away if you or your child do not feel well after having Flucelvax® Quad.
- Keep an updated record of your vaccinations. Keep any follow-up appointments with your doctor or clinic.

#### Driving or using machines

- Do not drive or use machines if you are feeling unwell after vaccination. Wait until any effects of the vaccine have worn off before you drive or using machines.

#### Looking after your medicine

Flucelvax® Quad is usually stored in the doctor's surgery or clinic, or at the pharmacy.

However, if you need to store Flucelvax® Quad:

- Keep it where children cannot reach it.
- Keep Flucelvax® Quad in the original pack until it is time for it to be given.
- Keep it in the refrigerator, between 2°C and 8°C. Do not freeze Flucelvax® Quad. Discard if the vaccine has been frozen.
- Freezing destroys the vaccine

#### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal. A doctor, nurse or pharmacist will dispose of any unused vaccine.

Do not use Flucelvax® Quad after the expiry date.

### 6. Are there any side effects?

All vaccines can have side effects. If you or your child 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, nurse 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>• local reaction around the injection site such as pain or tenderness, redness, swelling or the formation of hard lumps and bruising</li><li>• muscle aches or joint pain (not caused by exercise)</li><li>• flu-like symptoms, such as headache, tiredness or sleepiness,</li></ul>	<b>Speak to your doctor if you or your child have any of these less serious side effects and they worry you.</b>

fever, sore throat, runny nose, blocked nose, sneezing, cough, chills or shivering <ul style="list-style-type: none"> <li>• nausea, vomiting, diarrhoea</li> <li>• loss of appetite, change in eating habits, (children less than 6 years of age)</li> <li>• irritability (children less than 6 years of age)</li> <li>• fainting, collapse or feeling faint just before, during or after vaccination</li> </ul>	Mostly these are mild and short lived.
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## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• tingling of the hands or feet, or sudden numbness or weakness in the legs or arms</li> <li>• extensive swelling of the injected limb</li> <li>• generalised skin reactions including itching, bumps on the skin or non-specific rash</li> <li>• sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, (anaphylaxis)</li> <li>• shortness of breath, wheezing or trouble breathing</li> <li>• feeling weak or paralysed, or generally feeling sore or tender</li> <li>• rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting (shock)</li> <li>• very rarely, a serious disorder called Guillain-Barré syndrome (GBS) may occur. GBS is an autoimmune syndrome caused by your body's own immune system. GBS may make you feel weak; you may have difficulty moving around or you may experience numbness and tingling in your limbs.</li> <li>• fits, convulsions or seizures associated with fever</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you or your child notice any of these serious side effects.</b></p> <p>All of these side effects are rare.</p>

**Tell your doctor, nurse or pharmacist if you notice anything else that may be making you or your child 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 or your child 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 vaccine.

## 7. Product details

Flucelvax® Quad is only available with a doctor's prescription.

### What Flucelvax® Quad contains

<b>Active ingredient (main ingredient)</b>	<b>Influenza virus haemagglutinin</b> Each 0.5 mL contains 15 micrograms of influenza virus fragments from each of the following types of influenza virus: <ul style="list-style-type: none"> <li>• A/Sydney/5/2021 (H1N1)pdm09-like virus</li> <li>• A/Darwin/6/2021 (H3N2)-like strain</li> <li>• B/Austria/1359417/2021-like strain</li> <li>• B/Phuket/3073/2013-like strain</li> </ul> These strains have been recommended by the Australian Influenza Vaccine Committee for the 2023 Southern Hemisphere season.
<b>Other ingredients (inactive ingredients)</b>	Sodium chloride, Potassium chloride, Magnesium chloride hexahydrate, Dibasic sodium phosphate dihydrate, Monobasic potassium phosphate, Water for injections. <p>Flucelvax® Quad may also contain traces of beta-propiolactone, cetyltrimethylammonium bromide, and polysorbate 80, as residues of the manufacturing process.</p>

**Tell your doctor if you or your child have/has allergy to any of the above ingredients. Your doctor will decide if you can receive Flucelvax® Quad.**

**Flucelvax® Quad does not contain lactose, gluten, tartrazine, any other azo dyes, antibiotics or preservative.**

### What Flucelvax® Quad looks like

Flucelvax® Quad is a clear to slightly milky-white liquid in a pre-filled syringe (AUST R 319093 and AUST R 341450).

### Who distributes Flucelvax® Quad

Seqirus Pty Ltd  
ABN 26 160 735 035  
63 Poplar Road  
Parkville VIC 3052  
AUSTRALIA

This leaflet was prepared in January 2023.

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