

## 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.

**WARNING:** Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

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

Afluria<sup>®</sup> Quad contains the active ingredient influenza virus haemagglutinin. Afluria<sup>®</sup> Quad is a vaccine used to help prevent certain types of influenza or “flu”. It is for use only in people aged 5 years and older.

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

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

Tell your doctor, nurse or pharmacist if you or your child have ever had an 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 Afluria<sup>®</sup> Quad?](#) in the full CMI.

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

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

- Afluria<sup>®</sup> Quad is given as an injection, usually into the upper arm muscle by a doctor, nurse or pharmacist.
- Afluria<sup>®</sup> Quad is given once every year as follows:
  - Adults and children 5 years and older: one injection of 0.5 mL.
  - Children 5 years 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).

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

### 5. What should I know about being given Afluria<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 Afluria <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 Afluria<sup>®</sup> Quad?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects may include local reaction around the injection site, flu-like symptoms and muscle pain. Mostly these are mild and usually disappear within 3 days without treatment. 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.

**WARNING: Afluria® Quad vaccine is indicated for use only in persons aged 5 years and over. It must not be used in persons under 5 years**

# Afluria® Quad

Active ingredient(s): *influenza virus haemagglutinin*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Afluria® 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 Afluria® Quad.**

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

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

## 1. Why am I being given Afluria® Quad?

**Afluria® Quad contains the active ingredient influenza virus haemagglutinin.**

Afluria® Quad is a vaccine used to help prevent certain types of influenza or “flu”. It is for use in people aged 5 years and older.

Influenza is a sudden respiratory infection caused by the ‘flu’ virus. It is very contagious. It is usually spread from one person to another by small droplets from coughs and sneezes. The virus enters the nose or throat and may spread to the lungs. Influenza infection can lead to serious illness.

Vaccination with Afluria® Quad helps prevent infection with influenza and to control the spread of the disease. Influenza strains can change every year therefore previous influenza vaccinations are unlikely to give you protection against the current strains most common this year. You will therefore need to receive a vaccine against flu every year to lower the chance of catching the ‘flu’, especially if you are at risk.

Afluria® 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. Your body usually takes 2-3 weeks after vaccination to develop protection against influenza. Most people will produce enough antibodies against the influenza virus.

However, as with all vaccines, 100% protection cannot be guaranteed.

An influenza vaccine will only protect you against the types of influenza virus used to make it. 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).

The virus in Afluria® Quad has been killed therefore the vaccine cannot ‘give’ you the flu.

## 2. What should I know before being given Afluria® Quad?

### Warnings

**Do not use Afluria® Quad if:**

- Your child is under 5 years of age. Afluria® Quad is for use in people aged 5 years and older only.
  - You or your child have been severely allergic to any of the ingredients listed at the end of this leaflet or any previous influenza vaccine. 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 or skin rash, itching or hives.
- Always check the ingredients to make sure you can use this medicine.

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

have reacted to previous vaccination with any of the following:

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

have or have had any other medical conditions, especially the following:

- Guillain-Barré Syndrome (an illness affecting 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),

- take any medicines for any other condition, have allergy to
  - any other medicines,
  - to eggs, or egg proteins,
  - or any other substances, such as latex, food, preservatives or dyes.

Your doctor will decide if you can receive Afluria® Quad. A minor illness such as a cold should not be a problem but talk to your doctor about this if being vaccinated.

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. Influenza vaccination is recommended for pregnant women during any stage of pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor will discuss the potential risks and benefits of being given Afluria® Quad while you are breastfeeding.

### 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 Afluria® Quad and affect how it works.** These include medicines which lower the body's immune system, such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy).

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

Tell your doctor if you or your child have had any vaccines in the last 4 weeks. Afluria® Quad can be given at the same time as other vaccines.

**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 Afluria® Quad.**

### 4. How is Afluria® Quad given?

#### How much is given

Afluria® Quad is given once every year, as follows:

- Adults and children 5 years and over: one injection of 0.5 mL

- Children 5 years to 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 Afluria® Quad is given

Afluria® Quad is usually given before the start of the influenza season.

Vaccination should be repeated every year as new types of influenza virus can appear each year.

### How is Afluria® Quad given

Afluria Quad® is given as an injection, usually into your upper arm by a doctor, nurse or pharmacist.

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

#### Things you should do

Call your doctor straight away if you or your child do not feel well after having Afluria® Quad.

Keep an updated record of you and your child's 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 use machines.

#### Looking after your medicine

Afluria® Quad is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Afluria® Quad:

- **Keep it where young children cannot reach it.**
- Keep Afluria® 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 Afluria® Quad. Protect from light. 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 Afluria® 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.

The 2010 formulation of Fluvax® trivalent (three strain) influenza vaccine (manufactured by CSL, now Seqirus Pty Ltd) was associated with increased reports of febrile convulsions in children younger than 5 years.

Your child must not be given Afluria® Quad if they are under 5 years old as safety in this age group has not been established.

### 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 tenderness, bruising, redness, warmth, pain, swelling or the formation of hard lumps</li> <li>flu-like symptoms, such as headache, tiredness, fever, sore throat, runny nose, blocked nose, sneezing, cough, chills</li> <li>vomiting, nausea, diarrhoea</li> <li>aching muscles.</li> </ul>	<p><b>Speak to your doctor if you or your child have any of these less serious side effects and they worry you.</b></p> <p>Mostly these are mild and usually disappear within 3 days without treatment.</p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>An allergic reaction: Typical symptoms include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body,</li> <li>shortness of breath, wheezing or trouble breathing,</li> <li>tingling or numbness,</li> <li>a fit, convulsion or seizure, including convulsion associated with fever,</li> <li>bleeding or bruising more easily than normal</li> <li>little or no urine</li> <li>severe stabbing or throbbing nerve pain,</li> <li>neck stiffness, headache and high temperature associated with hallucinations, confusion, paralysis of part or all of the body, disturbances of behaviour, speech and eye movements, and sensitivity to light.</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</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 serious side effects are rare.</p>

system. GBS may make you feel weak; you may have difficulty moving around or you may experience numbness and tingling in your limbs.	
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**Tell your doctor, nurse or pharmacist if you or your child notice anything 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 experienced, 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

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

### What Afluria® Quad contains

<b>Active ingredient (main ingredient)</b>	<p><b>Influenza virus haemagglutinin</b></p> <p>Each 0.5 mL contains 15 micrograms from each of the following types of influenza virus:</p> <ul style="list-style-type: none"> <li>A/Sydney/5/2021 (H1N1)pdm09-like virus</li> <li>A/Darwin/9/2021 (H3N2)-like virus</li> <li>B/Austria/1359417/2021-like virus</li> <li>B/Phuket/3073/2013-like virus</li> </ul> <p>These strains have been recommended by the Australian Influenza Vaccine Committee for the 2023 Southern Hemisphere winter.</p>
<b>Other ingredients (inactive ingredients)</b>	<p>Sodium chloride, dibasic sodium phosphate, monobasic sodium phosphate, potassium chloride, monobasic potassium phosphate, calcium chloride dihydrate, water for injections</p> <p>May also contain traces of sodium taurodeoxycholate, egg protein (ovalbumin), sucrose, neomycin sulfate, polymyxin B sulfate, propiolactone and hydrocortisone.</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 Afluria® Quad.

Afluria® Quad does not contain lactose, gluten, tartrazine, any azo dyes, or latex.

### **What Afluria® Quad looks like**

Afluria® Quad is a clear to slightly opaque liquid, with some sediment that resuspends upon shaking, in glass pre-filled syringe with or without a needle for single use only (AUST R 262428 and AUST R 294907).

### **Who distributes Afluria® Quad**

Seqirus Pty Ltd

ABN 26 160 735 035

63 Poplar Road

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AUSTRALIA

This leaflet was prepared in October 2022.

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