

Afluria® 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.

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

1. Why am I using Afluria® Quad?

Afluria® Quad contains the active ingredient influenza virus haemagglutinin. Afluria® Quad is a vaccine that helps prevent influenza, often called “the flu”. Afluria® Quad is indicated for use only in persons aged 5 years and over.

For more information, see Section [1. Why am I using Afluria® Quad?](#) in the full CMI.

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

Tell your doctor, nurse or pharmacist if you or your child have ever had an allergic reaction to Afluria® Quad or any of the ingredients listed at the end of the CMI or any other influenza vaccine.

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® Quad?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Afluria® 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® Quad given?

- Afluria® Quad is given as an injection, usually into the muscle or under the skin of your upper arm by a doctor, nurse or pharmacist.
- Afluria® Quad is given once every year for adults and children 5 years and over in one injection of 0.5 mL.
- For children 5 to under 9 years old who are receiving influenza vaccine for the first time, it is recommended that a follow-up (booster) dose of Afluria® Quad is given at least 4 weeks after the first dose.

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

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.
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For more information, see Section [5. What should I know about being given Afluria® 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 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.

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 using 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 using 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 over.

Influenza is caused by infection with specific influenza viruses. New types of influenza viruses can appear each year. Afluria® Quad contains fragments of four different types of influenza virus. Each year the Australian Influenza Vaccine Committee decides which four types of viruses are most suitable to include in the vaccine.

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

Note: the vaccine will not protect you or your child from the other influenza viruses that Afluria® Quad does not contain.

Vaccination against influenza is recommended every year, for anyone wanting to lower their chance of catching influenza.

Afluria® Quad works by causing your body to protect itself against infection by the influenza viruses, types A and B, that are in the vaccine. The vaccine stimulates the body to make substances, called antibodies. Antibodies fight the influenza virus. If you have been vaccinated, when you come into contact with the influenza viruses in the

vaccine, your body is usually able quickly to destroy the virus. This prevents you from getting influenza.

Your body takes a few weeks after vaccination to fully develop protection against the influenza virus.

Protection against influenza generally requires one dose of Afluria® Quad. Some people including children who have not received influenza vaccination before may require two doses.

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

The chance of having a severe unwanted reaction after having Afluria® Quad is very small. Whereas, the risks of not being vaccinated against influenza may be very serious.

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

Warnings

Your child must not be given Afluria® Quad if they are under 5 years old. For the 2022 influenza season, Afluria® Quad is only for use in persons aged 5 years and over.

Do not use Afluria® Quad if:

you or your child are severely allergic to any of the ingredients listed at the end of this leaflet or to 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.

Always check the ingredients to make sure you can use this vaccine.

Do not have Afluria® Quad if you or your child have/has a temperature higher than 38.5°C.

Tell your doctor if you or your child:

have/has reacted to 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°C),
- severe skin reaction at the injection site, including severe bruising.

have/has an infection or temperature higher than 38.5°C.

have/has any other medical conditions, especially the following:

- low immunity due to ill-health, for example some blood disorders, malaria, kidney disease requiring dialysis, HIV/AIDS or cancer,
- low immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines, used to treat cancer (including radiation therapy),
- allergies or allergic reactions, including: runny, blocked or itchy nose; itchy rash or hives; swelling of the face, lips, mouth or tongue,
- Guillain-Barré Syndrome (GBS), an illness which affects the nervous system and causes paralysis.

have/has allergy to

- any other medicines,
- to eggs, or egg proteins,
- or any other substances, such as latex, food, preservatives or dyes.

Your doctor may decide to delay vaccination until the illness has passed. A minor illness such as a cold is not usually a reason to delay vaccination but talk to your doctor about this if being vaccinated. Your doctor will decide if you can receive Afluria® Quad.

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 having Afluria® Quad 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 Afluria® Quad and affect how it works. These include medicines which affect the body's immune response, such as corticosteroids, cyclosporin or some treatments for cancer (including radiation therapy).

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 as a single 0.5 mL dose for adults and children 5 years and over once every year. For children 5 to under 9 years old who are receiving influenza vaccine for the first time, it is recommended that a follow-up (booster) dose of Afluria® Quad is given at least 4 weeks after the first dose. If the follow-up dose is missed, talk to your doctor and arrange another visit as soon as possible.

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

It is given as an injection usually into the muscle or under the skin of your upper arm.

5. What should I know about having 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.

If you need to store Afluria® Quad:

- **Keep it where children cannot reach it.**
- Keep it in the refrigerator, between 2°C and 8°C. Do not freeze Afluria® Quad. Protect it from light. Note: Freezing destroys the vaccine.
- Keep Afluria® Quad in the original pack until it is time for it to be given.

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"> reaction around the injection site such as tenderness, bruising, redness, warmth, pain, swelling or the formation of hard lumps flu-like symptoms, such as headache, tiredness, fever, sore throat, runny nose, blocked nose, sneezing, cough, chills vomiting, nausea, diarrhoea aching muscles. 	<p>Speak to your doctor if you or your child have any of these less serious side effects and they worry you.</p> <p>Mostly these are mild and short-lived.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> 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, shortness of breath, wheezing or trouble breathing, tingling or numbness, a fit, convulsion or seizure, including convulsion associated with fever, bleeding or bruising more easily than normal little or no urine severe stabbing or throbbing nerve pain, 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. 	<p>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.</p> <p>All of these serious side effects are rare</p>

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

Tell your doctor, nurse or pharmacist if you or your child notice anything that makes you or your child feel unwell. Do not be alarmed by this list of possible side effects. You or your child may not experience any of them.

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. 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

Active ingredient (main ingredient)	Influenza virus haemagglutinin Each 0.5 mL contains 15 micrograms from each of the following types of influenza virus: A/Victoria/2570/2019 (H1N1)pdm09-like strain A/Darwin/9/2021 (H3N2)-like strain B/Austria/1359417/2021-like strain B/Phuket/3073/2013-like strain. These strains have been recommended by the Australian Influenza Vaccine Committee for the 2022 Southern Hemisphere winter.
Other ingredients (inactive ingredients)	Sodium chloride, Dibasic sodium phosphate, Monobasic sodium phosphate, Potassium chloride, Monobasic potassium phosphate, Calcium chloride dihydrate, Water for injections Afluria® Quad may also contain trace amounts of detergent (sodium taurodeoxycholate), egg protein (ovalbumin),

	sucrose, neomycin sulfate, polymyxin B sulfate, propiolactone and hydrocortisone.
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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
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AUSTRALIA

This leaflet was prepared in October 2021.

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