

Afluria[®] Quad

Inactivated Quadrivalent Influenza Vaccine (Split Virion)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about **Afluria[®] Quad** vaccine.

It does not contain all the available information.

It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines, including vaccines, have risks and benefits. Your doctor considers the risks of you or your child having **Afluria[®] Quad** vaccine and the benefits they expect it will have.

If you have any concerns about this vaccine, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may need to read it again.

What Afluria[®] Quad vaccine is used for

Afluria[®] Quad vaccine helps prevent influenza, often called “the flu”. Influenza is caused by infection with specific influenza viruses. New types of influenza viruses can appear each year. **Afluria[®] Quad** vaccine 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** vaccine does not contain.

Afluria[®] Quad vaccine is a prescription only medicine. This year (2019) the viruses are A/Michigan/45/2015 (H1N1) pdm09 – like virus, A/Switzerland/8060/2017 (H3N2) – like virus, B/Colorado/06/2017 and B/Phuket/3073/2013 – like virus.

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

How Afluria[®] Quad vaccine works

Afluria[®] Quad vaccine 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** vaccine. 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** vaccine is very small. Whereas, the risks of not being vaccinated against influenza may be very serious.

Before you or your child are given Afluria[®] Quad vaccine

When you or your child must not be given Afluria[®] Quad vaccine

Your child must not be given Afluria[®] Quad vaccine if they are under 5 years old. For the 2019 influenza season, Afluria[®] Quad vaccine is only for use in children aged 5 years and over.

Do not have Afluria[®] Quad vaccine if you or your child has previously had a severe allergic reaction to:

- any influenza vaccine
- 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.

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

Do not have Afluria[®] Quad vaccine after the expiry date printed on the packaging.

If you are not sure whether you or your child should have Afluria[®] Quad vaccine, talk to

your doctor, nurse or pharmacist.

Before you or your child are given Afluria® Quad vaccine

Tell your doctor if in the past 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.

Tell your doctor if you or your child have/has an infection or temperature higher than 38.5°C.

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.

Tell your doctor if in the past you or your child have/has had any 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.

Tell your doctor if you or your child have allergies to:

- any other medicines

- any other substances, such as latex, foods, preservatives or dyes.

Tell your doctor if you are pregnant, or are planning to become pregnant.

Your doctor will discuss the potential risks and benefits of having **Afluria® Quad** vaccine during pregnancy, and advise on the timing of **Afluria® Quad** vaccination with regards to pregnancy.

Tell your doctor if you are breast-feeding.

Your doctor will discuss the potential risks and benefits of having **Afluria® Quad** vaccine while you are breast-feeding.

Taking other medicines

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

Some medicines and **Afluria® Quad** vaccine may interfere with each other.

The following medicines or treatments may affect how well **Afluria® Quad** vaccine works:

- medicines which affect the body's immune response, such as corticosteroids, cyclosporin or
- some treatments for cancer (including radiation therapy).

Your doctor, nurse or pharmacist will help you decide whether or not you or your child should have the vaccine.

Having other vaccines

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

Afluria® Quad vaccine can be given at the same time as other vaccines.

Your doctor will tell you if **Afluria® Quad** vaccine is to be given at the same time as another vaccine.

How Afluria® Quad vaccine is given

How it is given

Afluria® Quad vaccine is given by a doctor, nurse or pharmacist, as an injection into the muscle or under the skin of your upper arm.

Afluria® Quad vaccine should be given at facilities able to manage any allergic reaction. Allergy to **Afluria® Quad** vaccine is uncommon, but allergy to any vaccine may occur.

How much is given

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

- Adults and children 5 years and over: 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** vaccine is given 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.

Overdose is unlikely as your doctor or nurse gives you or your child the injection and it is pre-packed in individual single-use syringes.

If you have any concerns, ask your doctor, nurse or pharmacist.

When it is given

Afluria® Quad vaccine 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.

After having Afluria® Quad vaccine

Things you or your child must do

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

Keep any follow-up appointments with your doctor or clinic.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you or your child feel unwell after having the vaccine.

Afluria® Quad vaccine may have unwanted side effects in a few people. All medicines, including vaccines, can have side effects. Sometimes they are serious, most of the time they are not. You or your child may need medical treatment for some of the side effects.

The 2010 formulation of Fluvax® trivalent (three strain) influenza vaccine (manufactured by 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 vaccine if they are under 5 years old as safety in this age group has not been established.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

The following are the more common side effects of Afluria® Quad vaccine. Mostly these are mild and short-lived.

Tell your doctor, nurse or pharmacist if you or your child notice any of the following and they worry you:

- 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.

The following may be serious side effects and you or your child may need urgent medical attention. However, these side effects are rare.

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

- tingling or numbness.

The following are very serious side effects and you or your child may need urgent medical attention or hospitalisation. All of these side effects are rare.

If any of the following happen to you or your child, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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
- 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.

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.

Other side effects not listed 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.

Storing Afluria® Quad vaccine

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

If you need to store Afluria® Quad vaccine:

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

Afluria® Quad vaccine should not be used after the expiry date on the packaging.

Product description

What it looks like

Afluria® Quad vaccine is supplied in a glass pre-filled disposable syringe with or without a needle for single use only. Your doctor, nurse or pharmacist will give you or your child the injection.

Afluria® Quad vaccine is supplied in pack sizes of one or ten syringes. Not all presentations or pack sizes may be marketed.

Ingredients

Active ingredients:

Purified, inactivated virus fragments from influenza types:

- H1N1 strain 15 micrograms
- H3N2 strain 15 micrograms
- B strain 15 micrograms
- B strain 15 micrograms

for the Southern Hemisphere winter season 2019.

Other ingredients

- Sodium chloride
- Dibasic sodium phosphate
- Monobasic sodium phosphate
- Potassium chloride
- Monobasic potassium phosphate
- Calcium chloride dihydrate
- Water for injections

Afluria® Quad vaccine may also contain trace amounts of detergent (sodium taurodeoxycholate), egg protein (ovalbumin), sucrose, neomycin sulfate, polymyxin B sulfate and propiolactone.

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

Ask your doctor, nurse or pharmacist if you are unsure about anything or want more information about Afluria® Quadvaccine.

Name and Address of Sponsor

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

Registration numbers

AUST R 262428
AUST R 294907

Date of preparation

19 October 2018

AFLURIA® and Fluvax® are registered trademarks of Seqirus UK Limited or its affiliates.