

# Afluria<sup>®</sup> Quad

# Afluria<sup>®</sup> Quad Junior

Inactivated Quadrivalent Influenza Vaccine (Split Virion)

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about **Afluria<sup>®</sup> Quad / Afluria<sup>®</sup> Quad Junior** 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<sup>®</sup> Quad / Afluria<sup>®</sup> Quad Junior** 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<sup>®</sup> Quad / Afluria<sup>®</sup> Quad Junior vaccine is used for

**Afluria<sup>®</sup> Quad / Afluria<sup>®</sup> Quad Junior** 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<sup>®</sup> Quad / Afluria<sup>®</sup> Quad Junior** vaccine contains fragments of four different types of influenza virus. Each year the Australian Influenza Vaccine Committee and the New Zealand Ministry of Health 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<sup>®</sup> Quad / Afluria<sup>®</sup> Quad Junior** vaccine does not contain.

**Afluria<sup>®</sup> Quad / Afluria<sup>®</sup> Quad Junior** vaccine is a prescription only medicine. This year (2020) the viruses are A/Brisbane/02/2018 (H1N1)pdm09-like strain, A/South Australia/34/2019 (H3N2)-like strain, B/Washington/02/2019-like strain and B/Phuket/3073/2013-like strain.

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

### How Afluria<sup>®</sup> Quad / Afluria<sup>®</sup> Quad Junior vaccine works

**Afluria<sup>®</sup> Quad / Afluria<sup>®</sup> Quad Junior** 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<sup>®</sup> Quad / Afluria<sup>®</sup> Quad Junior** 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<sup>®</sup> Quad / Afluria<sup>®</sup> Quad Junior** 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<sup>®</sup> Quad / Afluria<sup>®</sup> Quad Junior vaccine

**When you or your child must not be given Afluria<sup>®</sup> Quad / Afluria<sup>®</sup> Quad Junior vaccine**

**Do not have Afluria<sup>®</sup> Quad / Afluria<sup>®</sup> Quad Junior vaccine if you or your child has previously had an allergic reaction to:**

- any influenza vaccine
- any of the ingredients listed at the end of this leaflet, excluding egg protein (ovalbumin)

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 / Afluria® Quad Junior vaccine if you or your child have/has a temperature higher than 38.5°C.**

**Do not have Afluria® Quad / Afluria® Quad Junior vaccine after the expiry date printed on the packaging.**

**If you are not sure whether you or your child should have Afluria® Quad / Afluria® Quad Junior vaccine, talk to your doctor, nurse or pharmacist.**

***Before you or your child are given Afluria® Quad / Afluria® Quad Junior 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
- eggs
- 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 / Afluria® Quad Junior** vaccine may interfere with each other.

The following medicines or treatments may affect how well

**Afluria® Quad / Afluria® Quad Junior** 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/has had any vaccines in the last 4 weeks.**

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

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

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**How Afluria® Quad / Afluria® Quad Junior vaccine is given**

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***How it is given***

**Afluria® Quad / Afluria® Quad Junior** vaccine is given by a doctor, nurse or pharmacist, as an injection into the muscle or under the skin of your upper arm (preferably). For infants, the injection is normally given into the muscle of the thigh.

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

***How much is given***

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

- Adults and children 3 years and over: one injection of 0.5 mL

- Children 6 months to 35 months: one injection of 0.25 mL

For children 6 months 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 / Afluria® Quad Junior** 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 / Afluria® Quad Junior** 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.

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## **After having Afluria® Quad / Afluria® Quad Junior vaccine**

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### ***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.**

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## **Side effects**

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

**Afluria® Quad / Afluria® Quad Junior** 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.

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

The following are the more common side effects of **Afluria® Quad / Afluria® Quad Junior** 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
- irritability / loss of appetite.

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.

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## **Storing Afluria® Quad / Afluria® Quad Junior vaccine**

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

If you need to store **Afluria® Quad / Afluria® Quad Junior** vaccine:

- **Keep it where children cannot reach it**
- **Keep it in the refrigerator, between 2°C and 8°C. Do not freeze Afluria® Quad / Afluria® Quad Junior vaccine. Protect it from light.**

**Note:** Freezing destroys the vaccine.

- **Keep Afluria® Quad / Afluria® Quad Junior vaccine in the original pack until it is time for it to be given.**

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

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## Product description

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### *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. It contains a 0.5 mL dose for persons 3 years of age and older. Your doctor, nurse or pharmacist will give you or your child the injection.

**Afluria® Quad Junior** vaccine is supplied in a glass pre-filled disposable syringe with or without a needle for single use only. It contains a 0.25 mL dose for children 6 months to 35 months of age. Your doctor, nurse or pharmacist will give your child the injection.

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

### *Ingredients*

Active ingredients:

**Afluria® Quad** vaccine contains 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 2020. **Afluria® Quad Junior** contains half these amounts.

Other ingredients

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

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

**Afluria® Quad / Afluria® Quad Junior** 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® Quad / Afluria® Quad Junior vaccine.**

### *Name and Address of Sponsor*

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### *Registration number*

Afluria® Quad: TT50-10075  
Afluria® Quad Junior:  
TT50-10075/2

### *Date of preparation*

06 November 2019

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