

Consumer Medicine Information

What is in this leaflet

Read all of this leaflet carefully before you are vaccinated.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you. Do not pass it on to others.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- What FluQuadri is and what it is used for
- Before you are given FluQuadri
- How FluQuadri is given
- Possible side effects
- Storing FluQuadri
- Further information

What FluQuadri is and what it is used for

FluQuadri is a vaccine. Vaccines are used to protect you against infectious diseases.

FluQuadri is recommended to help protect you against influenza. FluQuadri may be administered to persons aged 6 months and older, especially those who run an increased risk of influenza-associated complications.

Influenza (flu) is a disease caused by different types of virus. Influenza viruses can spread rapidly, especially in homes or institutions, where it can be very easy for someone to catch flu and spread the disease. The greatest risk of catching flu is during the cold months between May and October. Your doctor will be able to recommend the best time for you to be vaccinated. Flu is present every year, even when epidemics or outbreaks are not reported.

The vaccine will only help to prevent flu if it is caused by one of the four strains of virus contained in the vaccine, or other strains closely related to them. FluQuadri will not prevent flu if you are incubating the disease before vaccination or if it is caused by another virus.

You should also note that many germs can cause influenza-like illness and the vaccine will not protect you against these.

Previous injections of flu vaccine are unlikely to give you protection against the current strains of flu virus which are most common this year, so you will need to receive a vaccine against flu every year especially if you are at risk.

How it Works

FluQuadri works by helping the body to make antibodies. These antibodies help the body to recognise the flu virus and prevent the infection. It takes a few weeks for the body to produce these antibodies. The vaccine will protect you only against the influenza viruses contained in the vaccine (or other strains closely related to them). It will not protect you from viruses that are unrelated to those contained in the vaccine.

Before you are given FluQuadri

When you or your child must not be given it

Do not have FluQuadri

- If you or your child ever had a severe allergic reaction to any of the other ingredients of FluQuadri listed in the FURTHER INFORMATION section.
- If you or your child ever had a severe allergic reaction after getting any flu vaccine.
- Before speaking to your doctor, if you or your child has an acute illness with or without high temperature.

Take special care with FluQuadri

- **Tell your doctor if you or your child has or has had Guillain-Barré syndrome (severe muscle weakness) after getting a flu vaccine**
- **Tell your doctor if you or your child has or has had an immune response problem because the immune response to the vaccine may be diminished**
- **Tell your doctor if you are pregnant or breast feeding.**

Your doctor will discuss the possible risks and benefits of having FluQuadri during pregnancy or breastfeeding. Due to the known adverse consequences of influenza infection in pregnant women, health authorities recommend vaccination for pregnant women.

Your doctor should make sure the benefits of vaccination outweigh the risks when recommending FluQuadri.

Taking other medicines

- Medicines that may reduce your immune response: such as corticosteroids (for example prednisone), medicines used to treat cancer (chemotherapy), radiotherapy or other medicines affecting the immune system. Tell your doctor if you have been treated with such medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

Having other vaccines

- Your doctor will advise you if FluQuadri is to be given with another vaccine.

How FluQuadri is given

FluQuadri is administered to you by your doctor or your nurse.

Dose and Schedule

Adults and children 6 months of age and older: A single 0.5 mL injection of FluQuadri.

Children who have not been vaccinated against influenza before require a second injection a month later. Doses of influenza vaccine for infants and young children are decided by your doctor based on the official national recommendations.

Method of Administration

FluQuadri is injected into the muscles of the upper arm (preferably). For infants, the

injection is normally given into the muscle of the thigh.

Possible side effects

Like all medicines, FluQuadri can cause side effects, although not everybody gets them.

The most common local side effects of FluQuadri include:

- pain, tenderness, redness (erythema), swelling, bruising (ecchymosis) and hardness (induration) at the injection site

Systemic side effects include:

- feeling unwell (malaise)
- muscle aches (myalgia)
- headache
- shivering
- fever
- irritability, abnormal crying, drowsiness, appetite loss, cough, runny nose, vomiting (in children)

These side effects usually clear up within a few days. If events continue or become severe, please tell your doctor or pharmacist.

Other side effects not listed above have been reported occasionally with other flu vaccines and not directly with FluQuadri:

- inflammation of nerves leading to weakness, such as weakness of facial muscles (facial palsy) or visual disturbances (optic neuritis/neuropathy)
- fainting (syncope), dizziness, tingling or numbness of hands or feet (paraesthesia)
- temporary inflammation of nerves causing pain, paralysis and sensitivity disorders (Guillain-Barré syndrome [GBS])
- fits (convulsions) with or without fever
- severe allergic reaction (anaphylaxis)
- temporary reduction in the number of blood particles called platelets (thrombocytopenia), swollen glands in neck, armpit or groin (lymphadenopathy)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Storing FluQuadri

FluQuadri is usually stored in the doctor's surgery or clinic, or at the pharmacy.

However, if you need to store FluQuadri:

- Keep out of reach and sight of children.
- Keep FluQuadri in the original pack until it is time for it to be given.
- **Keep it in the refrigerator, store at 2C to 8C. Do not freeze FluQuadri.**

Do not use FluQuadri after the expiry date which is stated on the carton after EXP.

Do not have FluQuadri if the packaging is torn or shows signs of tampering.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Further Information

What FluQuadri contains

Ingredients

Active Ingredients:

FluQuadri contains 4 killed influenza virus strains:

- A/Michigan/45/2015 (H1N1)pdm09-like virus (A/ Michigan/45/2015 X-275)
- A/Singapore/ INFIMH-16-0019/2016 (H3N2)-like virus (A/Singapore/ INFIMH-16-0019/2016 NIB-104)
- B/Phuket/3073/2013-like virus (B/Phuket/3073/2013)
- B/Brisbane/60/2008-like virus (B/ Brisbane/60/2008)

The other ingredients include sodium chloride, dibasic sodium phosphate, monobasic sodium phosphate, octoxinol-9, water for injection, and traces of formaldehyde.

Other Ingredients:

FluQuadri contains less than 1 microgram ovalbumin (egg protein) per dose.

FluQuadri does not contain any antibiotics or preservative.

What FluQuadri looks like and contents of the pack

FluQuadri is supplied in:

- Prefilled syringe (clear syringe plunger rod), 0.5 mL

Name and Address of Australian Sponsor

sanofi-aventis australia pty ltd
Talavera Corporate Centre – Building D
12-24 Talavera Road
Macquarie Park NSW 2113
Australia
Tel: 1800 818 806

Name and Address of New Zealand Sponsor

sanofi-aventis new Zealand limited
Level 8
56 Cawley St
Ellerslie
Auckland
New Zealand
Tel: 0800 234 684

AUST R number

AUST R 213963 (FluQuadri)

Date of preparation

August 2019