

FluQuadri™

FluQuadri™ Junior

Inactivated Quadrivalent Influenza Vaccine (Split Virion)

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

In this leaflet:

- What FluQuadri/FluQuadri Junior are and what they are used for
- Before you are given FluQuadri/FluQuadri Junior
- How FluQuadri/FluQuadri Junior are given
- Possible side effects
- Storing FluQuadri/FluQuadri Junior
- Further information

What FluQuadri/FluQuadri Junior are and what they are used for

FluQuadri and FluQuadri Junior are vaccines. Vaccines are used to

protect you against infectious diseases.

FluQuadri and FluQuadri Junior are recommended to help protect you against influenza. FluQuadri may be administered to persons aged 36 months and older, especially who run an increased risk of influenza-associated complications. FluQuadri Junior is designed for use in children aged 6 to 35 months.

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/FluQuadri Junior 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 They Work

FluQuadri and FluQuadri Junior work 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/FluQuadri Junior

When you or your child must not be given it

Do not have FluQuadri/FluQuadri Junior

- If you or your child ever had a severe allergic reaction to:
 - Eggs or egg products
 - Any of the other ingredients of FluQuadri/FluQuadri Junior 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/FluQuadri Junior

- **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. Sanofi Pasteur is collecting information on pregnancy outcomes and the health of newborn following vaccination with FluQuadri during pregnancy. Women who receive FluQuadri during pregnancy are encouraged to contact Sanofi Pasteur directly or have their doctor contact Sanofi Pasteur at 1800 829 468 (in Australia) or 0800 727 838 (in New Zealand)

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

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/FluQuadri Junior is to be given with another vaccine.

How FluQuadri/FluQuadri Junior are given

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

Dose and Schedule

Adults and children over 35 months: A single 0.5 mL injection

Children 6 to 35 months: A single 0.25 mL injection

Some children require a second injection a month later.

Method of Administration

FluQuadri/FluQuadri Junior 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/FluQuadri Junior can cause side effects, although not everybody gets them.

The most common local side effects of FluQuadri/FluQuadri Junior 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, 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/FluQuadri Junior:

- 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 Junior

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

However, if you need to store FluQuadri/FluQuadri Junior:

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

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

Do not have FluQuadri/FluQuadri Junior 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/FluQuadri Junior contain

Ingredients

Active Ingredients:

FluQuadri/FluQuadri Junior 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 Junior contains less than 0.5 microgram ovalbumin (egg protein) per dose.

FluQuadri/FluQuadri Junior does not contain any antibiotics or preservative.

What FluQuadri/FluQuadri Junior look like and contents of the pack

FluQuadri is supplied in:

- Prefilled syringe (clear syringe plunger rod), 0.5 mL, for persons 36 months of age and older.

FluQuadri Junior is supplied in:

- Prefilled syringe (pink syringe plunger rod), 0.25 mL, for persons 6 months through 35 months of age.

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 Pty Ltd
Level 8
56 Cawley St
Ellerslie
Auckland
New Zealand
Tel: 0800 234 684

AUST R number

AUST R 213963 (FluQuadri)
AUST R 213964 (FluQuadri Junior)

Date of preparation

28 November 2017

fluq-fluq-jr-ccds2-cmiv2-07dec17