

FLUQUADRI

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 or pharmacist.

1. Why am I using Fluquadri?

Fluquadri is a vaccine. This vaccine helps to protect you against influenza (flu). Fluquadri is used to prevent flu in persons of 6 months of age and older.

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

2. What should I know before I use Fluquadri?

Do not use if you have ever had an allergic reaction to Fluquadri or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you 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 I use Fluquadri?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Fluquadri and affect how it works. Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other vaccines or medicines, including medicines obtained without a prescription.

For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Fluquadri?

Fluquadri is given by your doctor, nurse or pharmacist.

More instructions can be found in Section [4. How do I use Fluquadri?](#) in the full CMI.

5. What should I know while using Fluquadri?

Things you should do	<p>Tell your doctor, nurse or pharmacist before you receive the vaccine if you</p> <ul style="list-style-type: none">• are allergic to the active ingredients or any of the other ingredients in this vaccine.• are suffering from an illness.• have a bleeding problem or bruise easily.• ever fainted from an injection.• have or had Guillain-Barré syndrome (severe muscle weakness) after getting a flu vaccine.• have a known allergy to egg protein.
Looking after your medicine	<p>Fluquadri is usually stored in the surgery or clinic, or at the pharmacy. However, if you need to store Fluquadri:</p> <ul style="list-style-type: none">• keep in the fridge between 2-8°C. Do not freeze.

For more information, see Section [5. What should I know while using Fluquadri?](#) in the full CMI.

6. Are there any side effects?

Serious side effects can include severe allergic reactions, inflammation of nerves leading to weakness, fainting, dizziness, tingling or numbness of hands or feet. temporary inflammation of nerves, fits, temporary reduction in the number of platelets, swollen glands in neck, armpit or groin. **See your doctor immediately if you notice this.**

Common side effects include pain, tenderness, redness, swelling, bruising and hardness at the injection site, headache, muscle aches, feeling unwell, fever, shivering. In children, other common side effects include irritability, abnormal crying, drowsiness, appetite loss, cough, runny nose and vomiting.

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.

Fluquadri

Active ingredient(s): Influenza virus haemagglutinin

Consumer Medicine Information (CMI)

This leaflet provides important information about using Fluquadri. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Fluquadri.**

This vaccine can be given to adults and children so you may be reading this leaflet for you or for your child.

Where to find information in this leaflet:

- [1. Why am I using Fluquadri ?](#)
- [2. What should I know before I use Fluquadri?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Fluquadri?](#)
- [5. What should I know while using Fluquadri?](#)
- [6. Are there any side effects?](#)
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- [3. What if I am taking other medicines?](#)
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- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Fluquadri

Fluquadri contains the active ingredient influenza virus haemagglutinin.

Fluquadri is a vaccine for persons 6 months of age and older. This vaccine helps to protect you against influenza (flu).

When a person is given the vaccine, the immune system (the body's natural defence system) will produce its own protection against the influenza virus. None of the ingredients in the vaccine can cause flu.

Flu is a disease that can spread rapidly and is caused by different types of strains that can change every year. Therefore, this is why you might need to be vaccinated every year. The greatest risk of catching flu is during the cold months between June and September. If you were not vaccinated in the autumn, it is still sensible to be vaccinated up until the spring since you run the risk of catching flu until then. Your doctor will be able to recommend the best time to be vaccinated.

As with all vaccines, Fluquadri may not fully protect all persons who are vaccinated.

2. What should I know before I use Fluquadri?

Warnings

Do not use Fluquadri:

- if you are allergic to the active ingredients or any of the ingredients listed at the end of this leaflet. Symptoms of allergic reaction may include difficulty breathing, shortness of breath, swelling of the face, lips, throat or tongue, cold, clammy skin, palpitations, dizziness, weakness, fainting, rash or itching. If you are not sure if you are allergic, talk to your doctor, nurse or pharmacist before you receive Fluquadri.

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

Tell your doctor, nurse or pharmacist:

- if you have an acute illness with or without high temperature.
- If you have or have had an immune response problem because the immune response to the vaccine may be diminished.
- If you have a bleeding problem or bruise easily.
- If you have ever fainted from an injection. Fainting, sometimes with falling, can occur during, following, or even before, any injection with a needle.
- If you have or have had Guillain-Barré syndrome (severe muscle weakness) after getting a flu vaccine.
- If you have a known allergy to egg protein.

After vaccination, you 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.

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.

3. What if I am taking other medicines?

Some medicines may interfere with Fluquadri and affect how it works. Tell your doctor, nurse or pharmacist if

- you are taking, have recently taken or might take any other vaccines or medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Fluquadri.

4. How do I use Fluquadri?

How much to use

Fluquadri is given by your doctor, nurse or pharmacist as a 0.5 mL injection in the muscle in the upper arm (preferably). For infants, the injection is normally given into the muscle of the thigh.

Children who have not been vaccinated against influenza before requiring 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.

5. What should I know while using Fluquadri?

Things you should do

Call your doctor straight away if you:

You notice signs of allergic reaction may include difficulty breathing, shortness of breath, swelling of the face, lips, throat or tongue, cold, clammy skin, palpitations, dizziness, weakness, fainting, rash or itching.

Driving or using machines

Fluquadri has no or negligible effect on your ability to drive and use machine.

Looking after your medicine

Fluquadri is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Fluquadri:

- keep it where young children cannot reach it.
- keep Fluquadri 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.

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

Do not use Fluquadri if the packaging is torn or shows signs of tampering.

Getting rid of unwanted Medicine

Medicines including vaccines 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.

6. Are there any side effects?

All medicines can have side effects. If you 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 or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• pain, tenderness, redness, swelling, bruising and hardness at the injection site• feeling unwell• headache• muscle aches• fever• shivering• irritability, abnormal crying, drowsiness, appetite loss, cough, runny nose, vomiting (in children)	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• inflammation of nerves leading to weakness, such as weakness of facial muscles (facial palsy) or visual disturbance (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 Barre syndrome [GBS])• fits (convulsions) with or without fever• severe allergic reaction (anaphylaxis)• temporary reduction in the number of blood particles called platelets (thrombocytopenia),	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

swollen glands in neck, armpit or groin (lymphadenopathy)	
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sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113
Telephone: 1800 818 806

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

Reporting side effects

After you have received medical advice for any side effects you 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 medicine.

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7. Product details

This medicine is only available with a doctor's prescription.

What Fluquadri contains

Active ingredient (main ingredient)	Influenza virus haemagglutinin of the following strains <ul style="list-style-type: none">• A/Brisbane/02/2018 (H1N1)pdm09 - like strain (A/Brisbane/02/2018 IVR-190)• A/South Australia/34/2019 (H3N2) - like strain (A/South Australia/34/2019 IVR-197)• B/Washington/02/2019 - like strain (B/Washington/02/2019)• B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013)
Other ingredients (inactive ingredients)	Sodium chloride, dibasic sodium phosphate, monobasic sodium phosphate, water for injection, and traces of ovalbumin (egg protein), octoxinol-9 and formaldehyde.

Do not use this vaccine if you are allergic to any of these ingredients.

What Fluquadri looks like

FluQuadri suspension for injection is clear and slightly opalescent in colour.

Fluquadri is available in packs of 5 or 10 single dose (0.5 mL) pre-filled syringes with or without separate needles. Not all pack sizes may be marketed.

AUST R 213963

Who distributes Fluquadri

Name and Address of Australian sponsor