

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, nurse or pharmacist.

1. Why am I being given Fluad®?

Fluad® contains the active ingredient influenza virus haemagglutinin. Fluad® is a vaccine used to help prevent certain types of influenza or “flu”. It is for use in people aged 50 years and older only.

For more information, see Section [1. Why am I being given Fluad®?](#) in the full CMI.

2. What should I know before being given Fluad®?

Tell your doctor, nurse or pharmacist if you have ever had an allergic reaction to any influenza vaccine or any of the ingredients listed in Section [7. Product details](#).

Talk to your doctor, nurse or pharmacist if you have any other medical conditions or take any other medicines.

For more information, see Section [2. What should I know before being given Fluad®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Fluad® and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is Fluad® given?

Fluad® is given as an injection, usually into your upper arm muscle by a doctor, nurse or pharmacist.

Fluad® is given once every year, one injection of 0.5 mL.

More instructions can be found in Section [4. How is Fluad® given?](#) in the full CMI.

5. What should I know about being given Fluad®?

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|-----------------------------|---|
| Things you should do | Call your doctor, nurse or pharmacist straight away if you do not feel well after having Fluad®. Keep an updated record of your vaccinations. Keep any follow-up appointments with your doctor or clinic. |
|-----------------------------|---|

For more information, see Section [5. What should I know about being given Fluad®?](#) in the full CMI.

6. Are there any side effects?

Common side effects may include local reaction around the injection site, fatigue and headache. Mostly these are mild and usually disappear within 3 days without treatment. Serious side effects are rare.

Sudden signs of allergy may be a serious side effect. If you experience this, tell your doctor immediately. Typical symptoms include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body.

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.

Fluad®

Active ingredient(s): *influenza virus haemagglutinin*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I being given Fluad®?](#)
- [2. What should I know before being given Fluad®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Fluad® given?](#)
- [5. What should I know about being given Fluad®?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given Fluad®?

Fluad® contains the active ingredient influenza virus haemagglutinin.

Fluad® is an adjuvanted vaccine used to help prevent certain types of influenza or “flu”. It is for use in people aged 50 years and older only.

Influenza is a sudden respiratory infection caused by the ‘flu’ virus. It is very contagious. It is usually spread from one person to another by small droplets from coughs and sneezes. The virus enters the nose or throat and may spread to the lungs. Influenza infection can lead to serious illness.

Vaccination with Fluad® helps prevent infection with influenza and to control the spread of the disease. Influenza strains can change every year therefore previous influenza vaccinations are unlikely to give you protection against the current strains most common this year. You will therefore need to receive a vaccine against flu every year to lower the chance of catching the ‘flu’, especially if you are at risk. Influenza vaccination is particularly recommended for people aged 65 years and older and for people with medical conditions that increase their risk or influenza or associated complications.

Fluad® works by causing your body to produce its own protection against the three types of influenza virus from which it is made. It does this by making substances called antibodies in the blood that fight the influenza virus. Your body usually takes 2-3 weeks after vaccination to develop protection against influenza. Most people will produce enough antibodies against the influenza virus. However, as with all vaccines, 100% protection cannot be guaranteed.

An influenza vaccine will only protect you against the types of influenza virus used to make it. It will not protect you from other types of influenza virus or from infections with

other agents causing flu-like symptoms (such as the common cold).

The virus in Fluad® has been killed therefore the vaccine cannot ‘give’ you the flu.

2. What should I know before being given Fluad®?

Warnings

Do not use Fluad® if:

- You are under 50 years old. Fluad® is for use in persons 50 years and older only.
- You are severely allergic to any of the ingredients listed at the end of this leaflet or any previous influenza vaccine. 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 or skin rash, itching or hives.
- Always check the ingredients to make sure you can use this medicine.

Tell your doctor, nurse or pharmacist if you:

have reacted to previous vaccination with any of the following:

- severe allergic reaction (anaphylaxis),
- difficulty breathing,
- swelling of the throat,
- fainting or collapse,
- fits or convulsions,
- severe skin reaction at the injection site, including severe bruising.

have or have had any other medical conditions, especially the following:

- Guillain-Barré Syndrome (an illness affecting nerves resulting in weakness of muscles),
- lowered immunity due to diseases such as some blood disorders, malaria, kidney disease requiring dialysis, HIV/AIDS or cancer
- lowered immunity due to treatment with medicines such as corticosteroids, ciclosporin or other medicines used to treat cancer (including radiation therapy)
- take any medicines for any other condition
- have an infection or high temperature (greater than 40°C)

have allergy to

- any other medicines,
- eggs, or egg proteins
- or any other substances, such as latex, food, preservative or dyes.

Your doctor, nurse or pharmacist will decide if you can receive Fluad®. A minor illness such as a cold should not be

a problem but talk to your doctor about this if being vaccinated.

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

Fluad® is indicated for people aged 50 years and older only.

3. What if I am taking other medicines?

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

Some medicines may interfere with Fluad® and affect how it works. These include medicines which lower the immune system, such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy).

Your doctor, nurse or pharmacist will consider whether adjustment of your medication is necessary.

Tell your doctor, nurse or pharmacist if you have had any vaccines in the last 4 weeks. Fluad® can be given at the same time as other vaccines.

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

4. How is Fluad® given?

How much is given

Fluad® is given as a single 0.5 mL dose.

When Fluad® is given

Fluad® is usually given before the start of the influenza season or when recommended by your doctor, nurse or pharmacist.

Vaccination for influenza should be repeated every year as new types of influenza virus can appear each year.

How is Fluad® given

It is given as an injection, usually into your upper arm muscle by a doctor, nurse or pharmacist.

5. What should I know about being given Fluad®?

Things you should do

Call your doctor, nurse or pharmacist straight away if you do not feel well after having Fluad®.

Keep an updated record of your vaccinations.

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

Driving or using machines

Do not drive or use machines if you are feeling unwell after vaccination. Wait until any effects of the vaccine have worn off before you drive or use machines.

Looking after your medicine

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

- **Keep it where young children cannot reach it.**
- Keep Fluad® in the original pack until it is time for it to be given.
- Keep it in the refrigerator, between 2°C and 8°C. Do not freeze Fluad®. Protect from light. Discard if the vaccine has been frozen. Freezing destroys the vaccine.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal. A doctor, nurse or pharmacist will dispose of any unused vaccine.

Do not use Fluad® after the expiry date.

6. Are there any side effects?

All vaccines 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, nurse 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">• local reaction around the injection site such as redness, tenderness, pain, warmth, burning or stinging, swelling or the formation of hard lumps, and bruising• fatigue• headache• soreness, aching muscles or joints, muscle tenderness or weakness (not caused by exercise)• diarrhoea• chills• nausea• loss of appetite• vomiting• fever• fainting, collapse or feeling faint just before, during or after vaccination | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>Mostly these are mild and usually disappear within 3 days without treatment.</p> |

Serious side effects

| Serious side effects | What to do |
|---|---|
| <ul style="list-style-type: none"> abscess at the injection site skin rash, itchy spots or red lumps on the skin tingling swollen lymph nodes sudden signs of allergy such as 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 rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting (shock) fits or convulsions muscular weakness passing little or no urine headache and high temperature associated with hallucinations, confusion, paralysis of part or all of the body, disturbances of behaviour, speech and eye movements, stiff neck and sensitivity to light bleeding or bruising more easily than normal stabbing or throbbing nerve pain 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 | <p>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.</p> <p>All of these serious side effects are rare.</p> |

Tell your doctor, nurse 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 vaccine.

7. Product details

Fluad® is a prescription only medicine. It is available from your doctor or pharmacist.

What Fluad® contains

| | |
|---|--|
| Active ingredient (main ingredient) | <p>Influenza virus haemagglutinin</p> <p>Each 0.5 mL contains 15 micrograms from each of the following types of influenza virus:</p> <ul style="list-style-type: none"> A/Missouri/11/2025 (H1N1)pdm09-like virus A/Singapore/GP20238/2024 (H3N2)-like virus B/Austria/1359417/2021-like virus <p>These strains have been recommended by the Australian Influenza Vaccine Committee for the 2026 Southern Hemisphere winter.</p> |
| Other ingredients (inactive ingredients) | <p>Adjuvant: MF59C.1: containing squalene (of fish origin), polysorbate 80, sorbitan trioleate, sodium citrate dihydrate, citric acid monohydrate, water for injections.</p> <p>Other: sodium chloride, potassium chloride, monobasic potassium phosphate, dibasic sodium phosphate dihydrate, magnesium chloride hexahydrate, calcium chloride dihydrate, water for injections.</p> <p>May also contain traces of kanamycin sulfate, neomycin sulfate, egg proteins (ovalbumin), formaldehyde, cetrimonium bromide, sucrose, and hydrocortisone as residues of the manufacturing process.</p> |

Tell your doctor, nurse, or pharmacist if you have an allergy to any of the above ingredients. Your doctor, nurse or pharmacist will decide if you can receive Fluad®.

Fluad® does not contain lactose, gluten, tartrazine, any azo dyes, or preservative.

What Fluad® looks like

Fluad® is a milky-white liquid, in glass pre-filled syringe with or without a needle for single use only (AUST R 90339 and AUST R 306718).

Who distributes Fluad®

Seqirus Pty Ltd
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This leaflet was prepared in October 2025.

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