

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 Flucelvax[®]?

Flucelvax[®] contains the active ingredient influenza virus haemagglutinin. Flucelvax[®] is a vaccine used to help prevent certain types of influenza or “flu”. It is for use in people aged 6 months and older.

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

2. What should I know before being given Flucelvax[®]?

Tell your doctor, nurse or pharmacist if you or your child have ever had an allergic reaction to any influenza vaccine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you or your child 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 being given Flucelvax[®]?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Flucelvax[®] 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 Flucelvax[®] given?

- Flucelvax[®] is given as an injection, usually into your upper arm muscle by a doctor, nurse or pharmacist.
- In young children, the injection may be given in the thigh muscle of the leg.
- Flucelvax[®] is given once every year, as follows:
 - Adults and children 9 years and older: one injection of 0.5 mL.
 - Children 6 months to less than 9 years of age: One or two 0.5 mL doses. Children less than 9 years of age who have not been previously vaccinated against influenza, should receive a second dose (at least 4 weeks after the first dose).

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

5. What should I know about being given Flucelvax[®]?

Things you should do	Call your doctor straight away if you or your child do not feel well after having Flucelvax [®] . 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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For more information, see Section [5. What should I know about being given Flucelvax[®]?](#) in the full CMI.

6. Are there any side effects?

Common side effects may include local reaction around injection site, headache, tiredness, muscle ache and nausea. Mostly these are mild and short lived. Serious side effects are rare.

Sudden signs of allergy may be a serious side effect. If you or your child experience this, tell your doctor, nurse or pharmacist 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 or your child have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Flucelvax[®]

Active ingredient(s): *influenza virus haemagglutinin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Flucelvax[®]. **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 Flucelvax[®].**

Where to find information in this leaflet:

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

1. Why am I being given Flucelvax[®]?

Flucelvax[®] contains the active ingredient influenza virus haemagglutinin.

Flucelvax[®] is a cell derived vaccine used to help prevent certain types of influenza or “flu”. It is for use in people aged 6 months and older.

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 Flucelvax[®] 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.

Flucelvax[®] 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 Flucelvax[®] has been killed, therefore the vaccine cannot ‘give’ you the flu.

2. What should I know before being given Flucelvax[®]?

Warnings

Do not use Flucelvax[®] if:

- Your child is under 6 months of age. Flucelvax[®] is for use in people aged 6 months and older only.
- You or your child have been severely allergic to any of the ingredients listed at the end of this leaflet or any previous influenza vaccines.
- 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, 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 or your child:

- 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 the 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,
 - high temperature (greater than 38°C),
 - have/has allergy to
 - any other medicines,
 - or any other substances, such as latex, food, preservatives or dyes.

Your doctor, nurse or pharmacist will decide if you can receive Flucelvax[®]. A minor illness such as a cold should not be a problem but talk to your doctor, nurse or pharmacist about it if being vaccinated.

After vaccination, you or your child 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

Influenza vaccination is recommended for pregnant women during any stage of pregnancy. Check with your doctor, nurse or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor, nurse or pharmacist if you are breastfeeding or intend to breastfeed.

Your doctor, nurse or pharmacist will discuss the potential risks and benefits of being given Flucelvax[®] while you are breast-feeding.

3. What if I am taking other medicines?

Tell your doctor, nurse or pharmacist if you or your child 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 Flucelvax[®] 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 an adjustment of medication is necessary.

Tell your doctor, nurse or pharmacist if you or your child have had any vaccines in the last 4 weeks. Flucelvax[®] 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 or your child are taking and if these affect Flucelvax[®].

4. How is Flucelvax[®] given?

How much is given

Flucelvax[®] is given, as follows:

- Adults and children 9 years and over: one injection of 0.5 mL
Children 6 months to less than 9 years of age: One or two 0.5 mL doses.
- Children less than 9 years of age who have not been previously vaccinated against influenza, should receive a second dose (at least 4 weeks after the first dose).

When is Flucelvax[®] given

- Flucelvax[®] 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 Flucelvax[®] given

- It is given as an injection, usually into your upper arm muscle by a doctor, nurse or pharmacist.
- In young children, the injection may be given in the thigh muscle of the leg.

5. What should I know about being given Flucelvax[®]?

Things you should do

Call your doctor, nurse or pharmacist straight away if you or your child do not feel well after having Flucelvax[®].

Keep an updated record of your and your child's 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

Flucelvax[®] is usually stored in the doctor's surgery or clinic, or at the pharmacy.

However, if you need to store Flucelvax[®]:

- **Keep it where young children cannot reach it.**
- Keep Flucelvax[®] 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 Flucelvax[®]. 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 Flucelvax[®] after the expiry date.

6. Are there any side effects?

All vaccines can have side effects. If you or your child 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 pain or tenderness, redness, swelling or the formation of hard lumps and bruising • muscle aches or joint pain (not caused by exercise) • flu-like symptoms, such as headache, tiredness or sleepiness, fever, sore throat, runny nose, blocked nose, sneezing, cough, chills or shivering • nausea, vomiting, diarrhoea • loss of appetite, change in eating habits, (children less than 6 years of age) • irritability (children less than 6 years of age) • fainting, collapse or feeling faint just before, during or after vaccination 	<p>Speak to your doctor, nurse or pharmacist if you or your child have any of these less serious side effects and they worry you.</p> <p>Mostly these are mild and short lived.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • tingling of the hands or feet, or sudden numbness or weakness in the legs or arms • extensive swelling of the injected limb • generalised skin reactions including itching, bumps on the skin or non-specific rash • 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, (anaphylaxis) • shortness of breath, wheezing or trouble breathing • feeling weak or paralysed, or generally feeling sore or tender • rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting (shock) • 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 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you or your child notice any of these serious side effects.</p> <p>All of these side effects are rare.</p>

<p>or you may experience numbness and tingling in your limbs.</p> <ul style="list-style-type: none"> • fits, convulsions or seizures associated with fever 	
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Tell your doctor, nurse or pharmacist if you notice anything else that may be making you or your child 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 or your child 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

Flucelvax[®] is a prescription only medicine. It is available from your doctor or pharmacist.

What Flucelvax[®] contains

Active ingredient (main ingredient)	<p>Influenza virus haemagglutinin</p> <p>Each 0.5 mL contains 15 micrograms of influenza virus fragments 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/Sydney/1359/2024 (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>Sodium chloride, Potassium chloride, Magnesium chloride hexahydrate, Dibasic sodium phosphate dihydrate, Monobasic potassium phosphate, Water for injections.</p> <p>May also contain traces of beta-propiolactone, cetyltrimethylammonium bromide, and polysorbate 80, as residues of the manufacturing process.</p>

Tell your doctor, nurse or pharmacist if you or your child have/has allergy to any of the above ingredients. Your doctor, nurse or pharmacist will decide if you can receive Flucelvax[®].

Flucelvax[®] does not contain lactose, gluten, tartrazine, any other azo dyes, antibiotics or preservative.

The sheath covering the needle may contain natural rubber latex, discuss this with your doctor if you or your child has an allergy to latex.

What Flucelvax® looks like

Flucelvax® is a clear to slightly milky-white liquid in a pre-filled syringe with or without a needle for single use only (AUST R 452626 and AUST R 452625).

Who distributes Flucelvax®

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AUSTRALIA

This leaflet was prepared in November 2025.

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