

# FLUARIX TETRA

## 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 receiving FLUARIX TETRA?

FLUARIX TETRA contains inactivated influenza virus as the active ingredient. FLUARIX TETRA is used to vaccinate against some strains of the influenza virus.

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

### 2. What should I know before I receive FLUARIX TETRA?

Do not use if you have ever had an allergic reaction to FLUARIX TETRA, any other influenza vaccine 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 receive FLUARIX TETRA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with FLUARIX TETRA 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 FLUARIX TETRA given?

- Your doctor, nurse or pharmacist will give you FLUARIX TETRA as an injection into your upper arm or upper thigh muscle.
- For adults and older children: FLUARIX TETRA is generally given as a single injection.
- For children aged between 6 months and 9 years of age who have not received an influenza vaccine before: a second dose is given 4 weeks after the first dose.

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

### 5. What should I know after receiving FLUARIX TETRA?

<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how FLUARIX TETRA affects you.</li><li>• FLUARIX TETRA may cause dizziness or light-headedness in some people.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• FLUARIX TETRA will normally be stored at the doctor's surgery or in the pharmacy.</li><li>• If you need to store FLUARIX TETRA, keep it in the refrigerator between 2°C and 8°C. Do not freeze.</li></ul>

For more information, see Section [5. What should I know after receiving FLUARIX TETRA?](#) in the full CMI.

### 6. Are there any side effects?

Side effects which have been reported following administration of FLUARIX TETRA include redness, swelling, a hard lump, soreness, bruising or itching around the injection site, pain at the injection site, fever, chills, shivering, sweating, dizziness, headache, a general feeling of being unwell, muscle aches and pain, joint pain, a loss of appetite, feeling sick, vomiting, diarrhoea, stomach pain, irritability, drowsiness, fatigue and rash.

Allergic reactions have also occurred following administration of FLUARIX TETRA. Allergy is rare and severe reactions will usually occur within the first few hours of vaccination. If this occurs go to the Emergency Department of the nearest hospital immediately.

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.

# FLUARIX TETRA

Active ingredient(s): *inactivated split influenza vaccine*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using FLUARIX TETRA. **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 FLUARIX TETRA.**

**Where to find information in this leaflet:**

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

## 1. Why am I receiving FLUARIX TETRA?

**FLUARIX TETRA contains inactivated split influenza virus as the active ingredient.**

**FLUARIX TETRA is used to help prevent certain types of influenza.**

The vaccine works by causing the body to produce its own protection (antibodies) against four different types of influenza virus.

The types of influenza antigen contained in FLUARIX TETRA may change from one year to another. Each year the Australian Influenza Vaccine Committee (AIVC) recommends which strains to include in the vaccine. This decision is based on the types of influenza virus thought most likely to occur during the next flu season.

Therefore, it is recommended to receive an influenza vaccination every year.

**FLUARIX TETRA will only protect you against the four types of influenza virus used to make the vaccine. It will not protect you from influenza caused by other types of influenza virus or from infections with other agents that cause flu-like symptoms (such as the common cold).**

FLUARIX TETRA cannot give you influenza when you receive it as the virus in the vaccine has been killed.

Influenza is an infectious illness and is spread by small droplets from the nose, throat or mouth of an infected person. The most common symptoms of influenza include fever, sore throat, runny nose, coughing, general aches and pains, headache, weakness and tiredness. Most people recover completely within one week.

The risk of serious complications (e.g. pneumonia and death) is greater in very young, very old and chronically ill people.

FLUARIX TETRA can be used in adults and children older than 6 months of age.

## 2. What should I know before I receive FLUARIX TETRA?

### Warnings

**Do not receive FLUARIX TETRA if:**

- you are allergic to FLUARIX TETRA, any other influenza vaccine, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- you or your child have a severe infection with a high temperature. Your doctor may decide to delay vaccination with FLUARIX TETRA until the illness has passed. A minor infection such as a cold is not usually a reason to delay vaccination but talk to your doctor, nurse or pharmacist about this before being vaccinated.

If you are unwell and cannot receive FLUARIX TETRA, talk to your doctor, nurse or pharmacist about when you can receive it.

### Check with your doctor if you/your child:

- have any other medical conditions
- have an immune deficiency condition
- have a bleeding disorder
- take any medicines for any other condition
- have had or have Guillain-Barre Syndrome, an inflammatory illness affecting the nerves and resulting in muscle weakness
- have received another vaccine
- are allergic to latex

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, nurse or pharmacist if you are pregnant or intend to become pregnant. They will discuss with you the risks and benefits involved in receiving FLUARIX TETRA.

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

It is not expected that FLUARIX TETRA will cause problems for breastfed babies.

### Fainting

Fainting can occur following, or even before, any needle injection. Tell the person giving you your injection if you or your child have ever fainted with a previous injection.

### 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 FLUARIX TETRA and affect how it works.**

- theophylline – a medicine used in chronic obstructive pulmonary disease and asthma
- phenytoin, phenobarbitone, carbamazepine – medicines used in the treatment of seizures, fits and epilepsy
- warfarin – a medicine used to thin your blood to prevent blood clots
- steroids, ciclosporin – medicines used to suppress the immune system

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

### 4. How is FLUARIX TETRA given?

**How much is given**

- Your doctor, nurse or pharmacist will give you FLUARIX TETRA as an injection
- For adults and children over the age of 6 months, 0.5 mL is given

**How it is given**

- FLUARIX TETRA is generally injected into the upper arm or upper thigh muscle

**When is it given**

- For adults and older children: FLUARIX TETRA is generally given as a single dose each year before the start of the influenza season which usually occurs during winter
- For children aged between 6 months and 9 years of age who have not received an influenza vaccine before: a second dose is given 4 weeks after the first dose

If a scheduled dose is missed, talk to your doctor or nurse and arrange another visit as soon as possible.

Vaccination against influenza should be repeated every year as different types of influenza virus strains can occur in different years.

**If you are given too much FLUARIX TETRA**

If you think that you have been given too much FLUARIX TETRA, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

### 5. What should I know after receiving FLUARIX TETRA?

**Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how FLUARIX TETRA affects you.**

FLUARIX TETRA may cause dizziness or light-headedness in some people.

**Looking after your medicine**

- FLUARIX TETRA will usually be stored at the doctor's clinic or at the pharmacy.
- If you need to store FLUARIX TETRA it is important to keep it in the refrigerator between 2°C and 8°C.
- **DO NOT FREEZE FLUARIX TETRA. FREEZING THIS MEDICINE WILL DESTROY THE VACCINE.**

Follow the instructions on the carton on how to take care of your medicine properly.

**Keep it where young children cannot reach it.**

**Getting rid of any unwanted medicine**

Do not use this medicine after the expiry date.

### 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.

Most side effects with FLUARIX TETRA are mild and usually clear up within a few days. These effects, as with other vaccines, usually occur around the injection site.

**Less serious side effects**

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• redness, swelling, a hard lump, soreness, bruising or itching around the injection site</li><li>• pain at the injection site</li><li>• fever, chills, shivering, sweating, dizziness, headache, malaise (generally feeling unwell)</li><li>• muscle aches and pain</li><li>• joint pain</li><li>• loss of appetite, feeling sick, vomiting, diarrhoea, stomach pain</li><li>• irritability</li><li>• drowsiness</li><li>• fatigue</li><li>• rash</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>transient swollen glands in the neck, armpit or groin</li> <li>painful swelling in the arms or legs</li> <li>vomiting</li> <li>flu-like symptoms such as a high temperature, sore throat, runny nose, cough and chills</li> <li>weakness of muscles</li> </ul> <p>In very young children, high fevers may result in convulsions (fits). It is advisable to monitor young children for high fevers post influenza vaccination.</p> <p>There have been rare reports of Guillain-Barre Syndrome (an inflammatory illness affecting nerves and resulting in muscle weakness). However these events have not been definitively linked to the use of influenza vaccines.</p> <ul style="list-style-type: none"> <li>allergic reaction</li> </ul> <p>Signs of an allergic reaction include:</p> <p>swelling of the limbs, face, eyes, inside of the nose, mouth or throat</p> <p>shortness of breath, breathing or swallowing difficulties</p> <p>hives, itching (especially of the hands or feet), reddening of the skin (especially around the ears) or severe skin reactions</p> <p>unusual tiredness or weakness that is sudden and severe</p> <p><b>Allergy to FLUARIX TETRA is rare. Severe reactions will usually occur within the first few hours of vaccination. If this occurs go to the Emergency Department of the nearest hospital immediately.</b></p>	<p><b>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.</b></p>

**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](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

### What FLUARIX TETRA contains

<b>Active ingredient (main ingredient)</b>	<p>A/ Victoria/4897/2022 (H1N1)pdm09-like strain</p> <p>A/ Thailand/8/2022 (H3N2)-like strain</p> <p>B/Austria/1359417/2021-like strain</p> <p>B/Phuket/3073/2013-like strain</p>
<b>Other ingredients (inactive ingredients)</b>	<p>dibasic sodium phosphate dodecahydrate</p> <p>dl-alpha-tocopheryl acid succinate</p> <p>formaldehyde (≤ 5 micrograms)</p> <p>gentamicin sulphate (trace amount)</p> <p>hydrocortisone (trace amount)</p> <p>magnesium chloride hexahydrate</p> <p>monobasic potassium phosphate</p> <p>octoxinol 10</p> <p>ovalbumin (≤ 0.05 micrograms)</p> <p>polysorbate 80</p> <p>potassium chloride</p> <p>sodium chloride</p> <p>sodium deoxycholate (trace amount)</p> <p>water for injections</p>

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

FLUARIX TETRA is not made with any human blood, blood products or substances made of human origin.

**Do not take this medicine if you are allergic to any of these ingredients.**

### What FLUARIX TETRA looks like

FLUARIX TETRA is a colourless to slightly opalescent suspension.

AUST R 200674 – pre-filled syringes available in packs of either 1 or 10 syringes without needles.

AUST R 242512 – pre-filled syringes available in packs of either 1 or 10 syringes without needles.

Not all presentations and pack sizes may be distributed.

**Who distributes FLUARIX TETRA**

GlaxoSmithKline Australia Pty Ltd  
Level 4, 436 Johnston Street  
Abbotsford, VIC 3067

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