Consumer Medicine Information

LifeWorks utilise three similar brands of influenza vaccine, which cover the same strains of influenza for the season. The Consumer Medicine Information for all 3 products is **attached below**.

If you would like to know which particular brand is being used at your onsite clinic, this information can be obtained by either:

1. Calling the LifeWorks office on 1300 657 644 and confirming which clinic you are attending, or;
2. Speaking to the nurse on the day of your clinic

INFLUVAC® TETRA

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about receiving this medicine, speak to your doctor, nurse or pharmacist.

1. Why am I receiving INFLUVAC TETRA?

INFLUVAC TETRA is an influenza vaccine containing inactivated fragments from four types of influenza virus. This type of vaccine is also known as a quadrivalent influenza vaccine. INFLUVAC TETRA is used to prevent certain types of influenza (commonly called the flu) and can be used in adults and children 6 months of age and older.

For more information, see Section 1. Why am I receiving INFLUVAC TETRA? in the full CMI.

2. What should I know before I receive INFLUVAC TETRA?

Do not receive INFLUVAC TETRA if you have had an allergic reaction to INFLUVAC TETRA, to any other influenza vaccine or to any of the ingredients listed at the end of the CMI.

Talk to your doctor, nurse or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

INFLUVAC TETRA is given by injection. Tell the doctor, nurse or pharmacist if you have ever fainted when receiving an injection.

INFLUVAC TETRA is usually stored at the pharmacy or at the doctor's clinic or surgery. If you need to store the vaccine, keep it in the fridge between 2°C to 8°C. Do not freeze.

For more information, see Section 2. What should I know before I receive INFLUVAC TETRA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with INFLUVAC TETRA and affect how it works.

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

4. How is INFLUVAC TETRA given?

- The doctor, nurse or pharmacist will give INFLUVAC TETRA as an injection.
- Generally, a single dose of 0.5 mL is given each year. For children less than 9 years of age who have not previously been vaccinated, a second dose of 0.5 mL should be given after an interval of at least 4 weeks.

More information can be found in Section 4. How is INFLUVAC TETRA given? in the full CMI.

5. What should I know after receiving INFLUVAC TETRA?

Driving or using machines	• INFLUVAC TETRA should not normally interfere with your ability to drive a car or operate machinery. • In some people vaccination can cause dizziness or light-headedness. Make sure you know how you react to INFLUVAC TETRA before you drive a car or operate machinery.

For more information, see Section 5. What should I know after receiving INFLUVAC TETRA? in the full CMI.

6. Are there any side effects?

Most unwanted effects with INFLUVAC TETRA are mild and usually clear up within a few days.

In adults and children, common side effects include pain and discomfort at the injection site, headache, tiredness, muscle and joint aches/pains, generally feeling unwell, shivering and sweating.

In children, other common side effects include stomach effects such as diarrhoea, vomiting and loss of appetite, irritability, drowsiness, and fever.

Serious side effects such as a serious allergic reaction may occur rarely.

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.

INFLUVAC® TETRA

Active ingredient(s): Quadrivalent Influenza Vaccine, surface antigen, inactivated (influenza virus haemagglutinin)

Consumer Medicine Information (CMI)

This leaflet provides important information about using INFLUVAC TETRA. **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 receiving INFLUVAC TETRA.**

Where to find information in this leaflet:

1. Why am I receiving INFLUVAC TETRA?

INFLUVAC TETRA is a quadrivalent influenza vaccine containing inactivated fragments from four types of influenza virus.

INFLUVAC TETRA is used to prevent certain types of influenza (commonly called the flu). The vaccine works by causing the body to produce its own protection (antibodies) against four different types of influenza virus.

Each year new types of influenza virus can appear, so every year INFLUVAC TETRA is changed to contain fragments of the new types of virus. Therefore, influenza vaccination is recommended every year.

Please note that INFLUVAC 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 causing flu-like symptoms (such as the common cold).

INFLUVAC TETRA can be used in adults and children over the age of 6 months.

2. What should I know before I receive INFLUVAC TETRA?

Warnings

Do not receive INFLUVAC TETRA if:

- You are allergic to any influenza vaccine or any of the ingredients listed at the end of this leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.
- You currently have a severe infection or fever. A minor infection such as a cold should not be a problem, but talk to your doctor, nurse or pharmacist about this before being vaccinated.

Check with your doctor, nurse or pharmacist if:

- You have received INFLUVAC TETRA before and became unwell.
- You have ever had an illness affecting the nervous system, especially Guillain-Barre Syndrome (GBS). If you have had GBS, you may be more likely to develop GBS following influenza vaccination than someone who has never had GBS.
- You have any medical conditions, such as an immune deficiency condition, thrombocytopenia, coagulation disorder or bleeding disorder.
- You have ever fainted or fallen or felt faint just before or after receiving an injection.

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 benefits and risks of receiving INFLUVAC TETRA when pregnant.

Tell your doctor, nurse or pharmacist if you are breast feeding. They will discuss the risks and benefits of vaccination however the vaccine is not expected to cause problems for breast-fed babies.

Storage

INFLUVAC TETRA is usually stored at the pharmacy, at the doctor's surgery or at the flu vaccination clinic.

If you need to store INFLUVAC TETRA, always:

- Keep it in the refrigerator stored between 2°C to 8°C. Do not freeze as freezing destroys the vaccine.
- Keep it where young children cannot reach it.
- Keep it in the original pack until it is time for it to be given.

Ask your pharmacist what to do with any leftover INFLUVAC TETRA that has expired or has not been used.

3. What if I am taking other medicines?

Tell your doctor, nurse or pharmacist if you have received another vaccine this year or if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

4. How is INFLUVAC TETRA given?

How it is given

The doctor, nurse or pharmacist will give INFLUVAC TETRA as an injection.

For some people with bleeding problems, the injection may need to be given under the skin (subcutaneously).

INFLUVAC TETRA should never be given into a vein (intravenously).

How much is given

For adults and children over 6 months of age, the doctor, nurse or pharmacist will give a single 0.5 mL dose of INFLUVAC TETRA.

For children less than 9 years of age who have not previously been vaccinated, a second dose of 0.5 mL should be given after an interval of at least 4 weeks.

When it is given

INFLUVAC TETRA is generally given as a single dose in autumn each year before the start of the flu season.

You should receive a repeated vaccination every year as new types of influenza virus can appear each year.

If the dose is missed

Talk to your doctor, nurse or pharmacist and arrange another visit as soon as possible.

5. What should I know after receiving INFLUVAC TETRA?

As with any vaccine, a protective immune response may not be elicited in all vaccines.

Driving or using machines

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

INFLUVAC TETRA should not normally interfere with your ability to drive a car or operate machinery. But in some people vaccination can cause dizziness or light-headedness. Make sure you know how you react to INFLUVAC TETRA before you drive a car, operate machinery, or do anything that could be dangerous if you are dizzy or light-headed.

6. Are there any side effects?

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well during or after receiving a dose of INFLUVAC TETRA.

All medicines can have side effects. Most unwanted effects with INFLUVAC TETRA are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site.

However, some side effects may need medical attention. As with all vaccines given by injection there is a very small risk of serious reactions. Allergy to INFLUVAC TETRA is rare. Any such severe reactions will usually occur within the first few hours of vaccination.

Ask your doctor, nurse or pharmacist if you have any questions about side effects.

Less serious side effects

Less serious side effects	What to do
Injection-site related: • Pain, redness, swelling, bruising or a hard lump around the injection site. **Other body reactions:** • Headache, tiredness, shivering, sweating, generally feeling unwell • Muscle and joint aches/pains **Additional side effects reported in children:** • Stomach upset, diarrhoea, vomiting, loss of appetite • Irritability, drowsiness, fever	**Speak to your doctor, nurse or pharmacist if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Allergic reaction: • Swelling of limbs, face, eyes, inside of nose, mouth or throat • Shortness of breath, breathing or swallowing difficulties • Hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions • Unusual tiredness or weakness that is sudden and severe.	**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.**

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 if you are in Australia or https://nzphvc.otago.ac.nz/reporting if you are in New Zealand. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available with a doctor's prescription or from a flu vaccination clinic.

What INFLUVAC TETRA contains

Active ingredients (main ingredient)	Each 0.5 mL dose of INFLUVAC TETRA contains 15 micrograms of each of the four types of influenza virus fragments: • A/Sydney/5/2021 (H1N1)pdm09-like strain • A/Darwin/9/2021 (H3N2)-like strain • B/Austria/1359417/2021-like (B/Victoria lineage) virus • B/Phuket/3073/2013-like (B/Yamagata lineage) virus
Other ingredients (inactive ingredients)	• Potassium chloride • Monobasic potassium phosphate • Dibasic sodium phosphate dihydrate • Sodium chloride • Calcium chloride dihydrate • Magnesium chloride hexahydrate • Water for injections
Potential allergens	The vaccine also contains limited quantities of egg protein (ovalbumin or chicken proteins), formaldehyde, cetrimonium bromide, sodium citrate, sucrose, gentamicin

	sulfate, traces of tylosine tartrate, hydrocortisone and polysorbate 80.

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

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

What INFLUVAC TETRA looks like

INFLUVAC TETRA is a clear, colourless liquid.

It is available in packs of 1 or 10 as a pre-filled (0.5 mL) glass syringe with 16 mm needle (AUST R 292237).

Who distributes INFLUVAC TETRA

Viatris Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

Distributed in New Zealand by:

Viatris Ltd

PO Box 11-183

Ellerslie AUCKLAND

www.viatris.co.nz

Telephone: 0800 168 169

INFLUVAC® TETRA is a Viatris company trade mark.

This leaflet was prepared in November 2022.

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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?

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 normally be stored at the doctor's surgery or in the pharmacy. • If you need to store FLUARIX TETRA, keep it in the refrigerator between 2°C and 8°C. Do not freeze.

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?

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
• redness, swelling, a hard lump, soreness, bruising or itching around the injection site • pain at the injection site • fever, chills, shivering, sweating, dizziness, headache, malaise (generally feeling unwell) • muscle aches and pain • joint pain • loss of appetite, feeling sick, vomiting, diarrhoea, stomach pain • irritability • drowsiness • fatigue • rash	**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
• transient swollen glands in the neck, armpit or groin • painful swelling in the arms or legs • vomiting • flu-like symptoms such as a high temperature, sore throat, runny nose, cough and chills • weakness of muscles In very young children, high fevers may result in convulsions (fits). It is advisable to monitor young children for high fevers post influenza vaccination. 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. • allergic reaction Signs of an allergic reaction include: swelling of the limbs, face, eyes, inside of the nose, mouth or throat shortness of breath, breathing or swallowing difficulties hives, itching (especially of the hands or feet), reddening of the skin (especially around the ears) or severe skin reactions unusual tiredness or weakness that is sudden and severe **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.**	**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.**

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.

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

Active ingredient (main ingredient)	A/Sydney/5/2021 (H1N1)pdm09-like virus A/Darwin/9/2021 (H3N2)-like virus B/Austria/1359417/2021-like (B/Victoria lineage) virus B/Phuket/3073/2013-like (B/Yamagata lineage) virus
Other ingredients (inactive ingredients)	dibasic sodium phosphate dodecahydrate dl-alpha-tocopheryl acid succinate formaldehyde (≤ 5 micrograms) gentamicin sulphate (trace amount) hydrocortisone (trace amount) magnesium chloride hexahydrate monobasic potassium phosphate octoxinol 10 ovalbumin (≤ 0.05 micrograms) polysorbate 80 potassium chloride sodium chloride sodium deoxycholate (trace amount) water for injections

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

This leaflet was prepared on 16 November 2022.

Version 11.0

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, nurse 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 being given 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 being given 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 is FluQuadri given?

FluQuadri is given by your doctor, nurse or pharmacist.

More instructions can be found in Section 4. How is FluQuadri given? in the full CMI.

5. What should I know about being given FluQuadri?

Things you should do	Tell your doctor, nurse or pharmacist after you or your child receive the vaccine • have signs of allergic reactions that 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.
Looking after your medicine	FluQuadri is usually stored in the surgery or clinic, or at the pharmacy. However, if you need to store FluQuadri: • keep in the fridge between 2-8°C. Do not freeze.

For more information, see Section 5. What should I know about being given 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 and 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, nurse 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?

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 the 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 influenza 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 being given 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 is FluQuadri given?

How much is given

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, require 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 about being given FluQuadri?

Things you should do

Call your doctor straight away if:

You notice signs of allergic reaction which 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

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

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 doctor, nurse or 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, nurse or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• 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, nurse or pharmacist if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• 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), swollen glands in neck, armpit or groin (lymphadenopathy)	**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.**

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 in Australia or in New Zealand at https://nzphvc.otago.ac.nz/reporting. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

What FluQuadri contains

Active ingredient **(main ingredient)**	Influenza virus haemagglutinin of the following strains • A/Sydney/5/2021 (H1N1)pdm09 - like strain (A/Sydney/5/2021, SAN-013) • A/Darwin/9/2021 (H3N2) - like strain (A/Darwin/9/2021, SAN-010) • B/Austria/1359417/2021- like strain (B/Michigan/01/2021, wild type) • B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013, wild type)
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.
Potential allergens	FluQuadri contains less than 1 microgram ovalbumin (egg protein) per dose.

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

FluQuadri does not contain any antibiotics or preservative.

FluQuadri syringes are not made with natural rubber latex.

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.

Who distributes FluQuadri

Distributed in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644

Freecall: 0800 283 684

Email: medinfo.australia@sanofi.com

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