

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

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 or a 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?

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
<p>Injection-site related:</p> <ul style="list-style-type: none"> • Pain, redness, swelling, bruising or a hard lump around the injection site. <p>Other body reactions:</p> <ul style="list-style-type: none"> • Headache, tiredness, shivering, sweating, generally feeling unwell • Muscle and joint aches/pains <p>Additional side effects reported in children:</p>	<p>Speak to your doctor, nurse or pharmacist if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • Stomach upset, diarrhoea, vomiting, loss of appetite • Irritability, drowsiness, fever 	

Serious side effects

Serious side effects	What to do
<p>Allergic reaction:</p> <ul style="list-style-type: none"> • 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. 	<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>

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.

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: <ul style="list-style-type: none">• A/Victoria/2570/2019 (H1N1)pdm09-like strain• A/Hong Kong/2671/2019 (H3N2)-like strain• B/Washington/02/2019-like (B/Victoria lineage) virus
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	<ul style="list-style-type: none"> • B/Phuket/3073/2013-like (B/Yamagata lineage) virus
<p>Other ingredients (inactive ingredients)</p>	<ul style="list-style-type: none"> • Potassium chloride • Monobasic potassium phosphate • Dibasic sodium phosphate dihydrate • Sodium chloride • Calcium chloride dihydrate • Magnesium chloride hexahydrate • Water for injections
<p>Potential allergens</p>	<p>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.</p>

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

Mylan Health Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Phone: 1800 314 527

INFLUVAC® TETRA is a Mylan company trade mark.

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