

# Vaxigrip Tetra

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## 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.

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### 1. Why am I using Vaxigrip Tetra?

Vaxigrip Tetra is a vaccine. This vaccine helps to protect you or your child against influenza (flu). Vaxigrip Tetra is used to prevent flu in persons of 6 months of age and older. If you are pregnant, one dose of vaccine given to you during pregnancy may protect your baby from birth to less than 6 months of age.

For more information, see Section [1. Why am I using Vaxigrip Tetra?](#) in the full CMI.

### 2. What should I know before I use Vaxigrip Tetra?

Do not use if you have ever had an allergic reaction to Vaxigrip Tetra 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 use Vaxigrip Tetra?](#) in the full CMI.

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

Some medicines may interfere with Vaxigrip Tetra 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.

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

### **4. How do I use Vaxigrip Tetra?**

Vaxigrip Tetra is given by your doctor, nurse or pharmacist.

More instructions can be found in Section [4. How do I use Vaxigrip Tetra?](#) in the full CMI.

## 5. What should I know while using Vaxigrip Tetra?

<b>Things you should do</b>	<p>Tell your doctor, nurse or pharmacist before you receive the vaccine if you</p> <ul style="list-style-type: none"><li>• are allergic to the active ingredients or any of the other ingredients in this vaccine.</li><li>• are suffering from an illness.</li><li>• have a bleeding problem or bruise easily.</li><li>• ever fainted from an injection.</li><li>• have or had Guillain-Barré syndrome (severe muscle weakness) after getting a flu vaccine.</li><li>• have a known allergy to egg protein.</li></ul>
<b>Looking after your medicine</b>	<p>Vaxigrip Tetra is usually stored in the surgery or clinic, or at the pharmacy. However, if you need to store Vaxigrip Tetra:</p>

- keep in the fridge between 2-8°C. Do not freeze.

For more information, see Section [5. What should I know while using Vaxigrip Tetra?](#) in the full CMI.

## 6. Are there any side effects?

Serious side effects can include severe allergic reactions, pain situated on the nerve route, fits, neurological disorders that may result in stiff neck, confusion, numbness, pain and weakness of the limbs, loss of balance, loss of reflexes, paralysis of part or all of the body and blood vessel inflammation which may result in skin rashes and in very rare cases temporary kidney problems. **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, shivering. In children, other common side effects include irritability, abnormal crying, drowsiness, appetite loss 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.

# Vaxigrip Tetra

**Active ingredient(s):** Influenza virus haemagglutinin

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Vaxigrip 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 Vaxigrip Tetra.**

**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 Vaxigrip Tetra?](#)
- [2. What should I know before I use Vaxigrip Tetra?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Vaxigrip Tetra?](#)
- [5. What should I know while using Vaxigrip Tetra?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Vaxigrip Tetra?

**Vaxigrip Tetra contains the active ingredient influenza virus haemagglutinin.**

Vaxigrip Tetra is a vaccine for persons 6 months of age and older. This vaccine helps to protect you or your child against influenza (flu). If you are pregnant, one dose of vaccine given to you during pregnancy may protect your baby from birth to less than 6 months of age.

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 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 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 flu until then. Your doctor will be able to recommend the best time to be vaccinated.

As with all vaccines, Vaxigrip Tetra may not fully protect all persons who are vaccinated.

## **2. What should I know before I use Vaxigrip Tetra?**

### **Warnings**

#### **Do not use Vaxigrip Tetra:**

- 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 Vaxigrip Tetra. 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 Vaxigrip Tetra during pregnancy or breastfeeding.

Vaxigrip Tetra can be used in all stages of pregnancy.

Vaxigrip Tetra may be used during breast-feeding.

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 Vaxigrip Tetra.

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

Some medicines may interfere with Vaxigrip Tetra 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 Vaxigrip Tetra 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 Vaxigrip Tetra.

## **4. How do I use Vaxigrip Tetra?**

### **How much to use**

Vaxigrip Tetra 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 less than 9 years old, 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 while using Vaxigrip Tetra?**

### **Things you should do**

#### **Call your doctor straight away if you:**

You notice signs 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.

#### **Driving or using machines**

Vaxigrip Tetra has no or negligible effect on your ability to drive and use machine.

#### **Looking after your medicine**

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

- keep it where young children cannot reach it.
- keep Vaxigrip Tetra 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 Vaxigrip Tetra.

Do not use Vaxigrip Tetra after the expiry date which is stated on the carton after EXP.

Do not use Vaxigrip Tetra if the packaging is torn or shows signs of tampering.

## Getting rid of any unwanted medicine

Medicines including vaccines should not be disposed of via wastewater or household waste. Ask your 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 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"><li>● pain, tenderness, redness, swelling, bruising and hardness at the injection site</li><li>● feeling unwell</li><li>● headache</li><li>● muscle aches</li><li>● fever</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● shivering</li> <li>● irritability, abnormal crying, drowsiness, appetite loss, vomiting (in children)</li> <li>● temporary reduction in the number of blood particles called platelets (thrombocytopenia), swollen glands in neck, armpit or groin (lymphadenopathy)</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● pain situated on the nerve route (neuralgia), fits (convulsion), neurological disorders that may result in stiff neck</li> <li>● tingling or numbness of hands or feet (paraesthesia)</li> <li>● confusion, numbness, pain and weakness of the limbs, loss of balance, loss of</li> </ul>	<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>

<b>Serious side effects</b>	<b>What to do</b>
<p>reflexes, paralysis of part or all of the body (encephalomyelitis, neuritis, Guillain-Barre syndrome)</p> <ul style="list-style-type: none"> <li>● tingling or numbness of the hands or feet (paraesthesia)</li> <li>● blood vessel inflammation (vasculitis) which may result in skin rashes and in very rare cases temporary kidney problems</li> <li>● severe allergic reaction (anaphylaxis)</li> <li>● swollen glands in the neck, armpit or groin (lymphadenopathy)</li> <li>● short-term low blood platelet count (transient thrombocytopenia)</li> </ul>	

**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.

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Vaxigrip Tetra contains

<b>Active ingredient (main ingredient)</b>	<p>Influenza virus haemagglutinin of the following strains</p> <ul style="list-style-type: none"><li>● A/Victoria/2570/2019 (H1N1)pdm09 - like strain (A/Victoria/2570/2019, IVR-215)</li><li>● A/Hong Kong/2671/2019 (H3N2) - like strain (A/Hong Kong/2671/2019, IVR-208)</li><li>● B/Washington/02/2019 - like strain (B/</li></ul>
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	<p>Washington/02/2019, wild type)</p> <ul style="list-style-type: none"> <li>• B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013, wild type)</li> </ul>
<p><b>Other ingredients (inactive ingredients)</b></p>	<p>Sodium chloride, potassium chloride, dibasic sodium phosphate dihydrate, monobasic potassium phosphate, water for injections, and traces of ovalbumin (egg protein), neomycin, octoxinol-9 and formaldehyde.</p>

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

## **What Vaxigrip Tetra looks like**

Vaxigrip Tetra suspension for injection is clear and slightly opalescent in colour.

Vaxigrip Tetra is available in packs of 1 or 10 single dose (0.5 mL) pre-filled syringes with attached needle or with one separate needle or no needle provided per syringe.

AUST R 315082 – prefilled syringe with attached needle\*

AUST R 299922 – prefilled syringe needle free \*

\*Not all pack sizes may be marketed.

## **Who distributes Vaxigrip Tetra**

### **Name and Address of Australian sponsor**

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Telephone: 1800 818 806

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