

# Adacel® Polio

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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.

### 1. Why am I using Adacel Polio?

Adacel Polio contains the active ingredients diphtheria toxoid, tetanus toxoid, pertussis toxoid, pertussis filamentous haemagglutinin, pertussis fimbriae 2+3, pertactin and poliovirus types 1,2 and 3 (Vero). Adacel Polio is used to help to protect you or your child against whooping cough (pertussis), tetanus, diphtheria and polio. For more information, see Section [1. Why am I using Adacel Polio?](#) in the full CMI.

### 2. What should I know before I use Adacel Polio?

Do not use if you or your child has ever had an allergic reaction to Adacel Polio or any of the ingredients listed at the end of the CMI, or if you or your child ever had a disease of brain without an apparent cause within 7 days of a previous pertussis, tetanus or diphtheria vaccination. 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 Adacel Polio?](#) in the full CMI.

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

Some medicines may interfere with Adacel Polio 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 do I use Adacel Polio?**

Adacel Polio is given by your doctor, nurse or pharmacist. More instructions can be found in Section [4. How do I use Adacel Polio?](#) in the full CMI.

### **5. What should I know while using Adacel Polio?**

<b>Things you should do</b>	<p>Tell your doctor, nurse or pharmacist before you receive the vaccine if you or your child</p> <ul style="list-style-type: none"><li>• is allergic to the active ingredients or any of the other ingredients in this vaccine.</li></ul>
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	<ul style="list-style-type: none"> <li>• is suffering from an illness</li> <li>• has a bleeding problem or bruise easily.</li> <li>• ever fainted from an injection</li> <li>• has not previously received the complete course of tetanus and diphtheria vaccination</li> <li>• had a disease of brain without an apparent cause within 7 days of a previous pertussis, tetanus or diphtheria vaccination.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Adacel Polio should not normally interfere with your ability to drive or operate machinery. However, it may cause light-headedness, tiredness, drowsiness in some people.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Adacel Polio is usually stored in the surgery or clinic, or at the pharmacy. However, if you need to store Adacel Polio, keep in the</li> </ul>

	fridge between 2-8°C. Do not freeze.
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For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

## 6. Are there any side effects?

Common side effects include a local reaction around the injection site such as bruising, redness, itchiness, tenderness, pain or discomfort, warmth, burning or stinging, swelling or the formation of hard lumps or scars, rash, headaches, tiredness, weakness or fatigue, fever, rigors, soreness, aching muscles, muscle tenderness or weakness (not caused by exercise), joint pain or swelling, irritability, nausea and vomiting, diarrhoea.

Serious side effects can include red, itchy rash or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing, a temporary inflammation of the nerves, causing pain, weakness, and paralysis in the extremities and often progressing to the chest and face, severe pain and decreased mobility of arm and shoulder, fits or convulsion, fainting, tingling or numbness of the hands or decreased feeling or sensitivity of the vaccinated arm, a paralysed nerve in the face, dizziness, generally feeling unwell, pale skin, stomach pain . See your doctor immediately if you notice this. 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.



# Adacel Polio®

**Active ingredient(s):** *Pertussis Vaccine - Acellular and Diphtheria and Tetanus Toxoids (Adsorbed) Combined with Inactivated Poliovirus Type 1, 2 and 3 (Vero cell)*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Adacel Polio. **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 Adacel Polio.**

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

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

## 1. Why am I using Adacel Polio?

Adacel Polio contains the active ingredients diphtheria toxoid, tetanus toxoid, pertussis toxoid, pertussis filamentous haemagglutinin, pertussis fimbriae 2+3, pertactin and poliovirus types 1,2 and 3 (Vero).

Adacel Polio is a vaccine used to help to protect you or your child against whooping cough (pertussis), tetanus, diphtheria and polio.

Adacel Polio works by causing the body to produce its own protection against whooping cough, tetanus, diphtheria, and polio. It does this by making substances called antibodies in the blood, which fight the bacteria and toxins that cause these diseases. If a vaccinated person comes into contact with these bacteria and toxins, the body is usually ready to destroy them.

It usually takes several weeks after vaccination to develop protection against these diseases.

Use of Adacel Polio during pregnancy allows antibodies to be passed to the baby in the womb from the pregnant woman to protect the baby from whooping cough during the first few months of life.

Most people will produce enough antibodies against these diseases. However, as with all vaccines, 100% protection cannot be guaranteed.

The vaccine will not give you or your child any of these diseases.

The chance of a severe reaction from Adacel Polio is very small, but the risks from not being vaccinated against these diseases may be very serious. Polio, whooping cough, tetanus and diphtheria cause significant sickness and sometimes death in unvaccinated infants, children, and adults.

This vaccine is for use as a booster in adults, adolescents and children aged four years and older who have previously received childhood immunisation. Children from four to six years of age should have already received four doses of whooping cough, tetanus, diphtheria and polio vaccine. Adacel Polio is not intended for primary immunisation.

## **2. What should I know before I use Adacel Polio?**

### **Warnings**

#### **Do not use Adacel Polio if you or your child:**

- had an allergic reaction to Adacel Polio or any of the ingredients listed at the end of this leaflet.
- had an allergic reaction to another vaccine designed to protect against pertussis, tetanus, diphtheria or polio.
- had serious encephalopathy (disease of brain) without an apparent cause within 7 days of a previous pertussis, tetanus or diphtheria vaccination.
- Always check the ingredients to make sure you or your child can receive this vaccine.

Adacel Polio is not recommended for use in children under 4 years.

#### **Check with your doctor if you or your child:**

- Has or ever had any other medical conditions, such as:



- a poor or reduced immune system due to medication (e.g. steroid or medicines used to treat cancer (including radiation therapy) diseases such as some blood disorders, malaria, kidney disease requiring dialysis, HIV/AIDS or cancer
- a progressive illness affecting the brain/nerves or uncontrolled fits
- takes any medicines for any other condition
- has reacted to previous vaccination with any of the following: life-threatening allergic reaction, fainting or collapse, shock-like state or being unresponsive for a long period of time, fits or convulsions, high temperature (greater than 40°C), crying or screaming lasting for more than 3 hours, severe skin reaction at the injection site, including severe bruising.
- had a Guillain-Barré syndrome (temporary loss of movement and feeling in all or part of the body) within 6 weeks of a previous dose of a tetanus containing vaccine.
- has not previously received the complete course of tetanus and diphtheria vaccination.
- has an infection or high temperature. Your doctor may decide to delay vaccination until the illness has passed. A mild illness, such as a cold, is not usually a reason to delay vaccination.
- Has any allergies to any vaccines, any other medicines or any other substance such as foods, preservatives or dyes.

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**

Tell your doctor or nurse if you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby. Your doctor will help you decide if you should receive Adacel Polio during pregnancy.

Adacel Polio may be administered during pregnancy for prevention of pertussis in young infants.

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

Tell your doctor 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.

## **Having other vaccines**

Tell your doctor if you or your child has had any vaccines in the last 4 weeks.

Your doctor will advise you if Adacel Polio is to be given with another vaccine.

Your doctor and pharmacist may have more information on medicines and vaccines to be careful with or avoid during vaccination with Adacel Polio.

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

## **4. How do I use Adacel Polio?**

Adacel Polio is given as an injection, usually into your upper arm muscle by a doctor or nurse.

### **How much is given**

- The dose of Adacel Polio is a single dose of 0.5mL.

### **When to receive Adacel Polio**

- Adacel Polio is generally given whenever a booster dose of tetanus and diphtheria is required and where a booster dose of whooping cough and polio is considered necessary.

## **5. What should I know while using Adacel Polio?**

### **Things you should do**

Keep an updated record of your vaccinations.

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

- does not feel well after having Adacel Polio

- has any 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**

Adacel Polio should not normally interfere with your ability to drive or operate machinery. However, it may cause light-headedness, tiredness, drowsiness in some people.

## **Looking after your medicine**

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

- keep Adacel Polio 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 Adacel Polio.

Do not use Adacel Polio after the expiry date which is stated on the carton after EXP.

Do not use Adacel Polio if the packaging is torn or shows signs of tampering.

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

## 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.

## 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>• local reaction around the injection site such as bruising, redness, itchiness, tenderness, pain or discomfort, warmth, burning or stinging, swelling or the formation of hard lumps or scars</li><li>• rash</li><li>• headaches</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>● tiredness, weakness or fatigue</li> <li>● fever</li> <li>● rigors</li> <li>● soreness, aching muscles, muscle tenderness or weakness (not caused by exercise)</li> <li>● joint pain or joint swelling</li> <li>● irritability</li> <li>● nausea and vomiting</li> <li>● diarrhoea</li> <li>● These are the more common side effects of Adacel Polio. Mostly these are mild and short-lived. If however, these symptoms persist for more than 1 week, then you should tell your doctor.</li> </ul>	

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• dizziness</li> <li>• generally feeling unwell</li> <li>• pale skin</li> <li>• stomach pain</li> <li>• pain in the vaccinated arm</li> <li>• swollen glands in the neck, armpit or groin</li> <li>• large reactions at the injection site (larger than 5 cm), including extensive limb swelling from the injection site beyond one or both joints. These reactions start within 48 hours after vaccination, may be associated with redness, warmth, tenderness or pain at the injection site, and get better within 3-5 days without the need for treatment.</li> </ul> <p>The following side effects are very serious. You or your child may need</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>

<b>Serious side effects</b>	<b>What to do</b>
<p>urgent medical attention or hospitalisation:</p> <ul style="list-style-type: none"> <li>• sudden signs of allergy such as red, itchy rash or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing</li> <li>• a temporary inflammation of the nerves, causing pain, weakness, and paralysis in the extremities and often progressing to the chest and face</li> <li>• severe pain and decreased mobility of arm and shoulder</li> <li>• fits or convulsion</li> <li>• fainting</li> <li>• inflammation of spinal column</li> <li>• tingling or numbness of the hands or decreased feeling or sensitivity of the vaccinated arm</li> </ul>	



Serious side effects	What to do
<ul style="list-style-type: none"> <li>a paralysed nerve in the face</li> </ul> <p>All of these side effects are rare.</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.

## 7. Product details

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

### What Adacel Polio contains

<b>Active ingredients</b> <b>(main ingredient)</b>	not less than 2 IU (2 LF) diphtheria toxoid
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	<p>not less than 20 IU (5 LF) tetanus toxoid</p> <p>2.5 micrograms pertussis toxoid</p> <p>5 micrograms pertussis filamentous haemagglutinin</p> <p>3 micrograms pertussis pertactin</p> <p>5 micrograms pertussis fimbriae 2 + 3</p> <p>40 DAgU Poliovirus inactivated type 1</p> <p>8 DAgU Poliovirus inactivated type 2</p> <p>32 DAgU Poliovirus inactivated type 3</p>
<b>Other ingredients (inactive ingredients)</b>	<p>aluminium phosphate</p> <p>phenoxyethanol</p> <p>polymyxin B sulfate</p> <p>neomycin</p> <p>streptomycin sulfate</p> <p>formaldehyde</p> <p>glutaral</p>

	polysorbate 80 water for injections Medium Hanks 199 without phenol red (including phenylalanine)
The manufacture of this product includes exposure to bovine 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	

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

## **What Adacel Polio looks like**

Adacel Polio is a sterile, uniform cloudy, white suspension for injection.

Aust R 106565 - Vial (not marketed)

Aust R 106576 - Syringe

## **Who distributes Adacel Polio**

Australia:

sanofi-aventis australia Pty Ltd

12 - 24 Talavera Road

Macquarie Park

NSW 2113, Australia

Tel: 1800 816 806

New Zealand:

sanofi-aventis new zealand limited

Level 8,

56 Cawley St

Ellerslie

Auckland

New Zealand

Tel: 0800 727 838

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