

## 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?

Adacel is a vaccine. It is used to help prevent whooping cough (pertussis), tetanus and diphtheria in persons aged 10 years and over as a booster following primary immunisation. Use of Adacel 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.

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

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

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

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

Some medicines may interfere with Adacel 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?

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

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

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

|                                    |                                                                                                                                                                                                                                                                                                                                                                                                                             |
|------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Things you should do</b>        | <p>Tell your doctor or nurse before you receive this vaccine if you:</p> <ul style="list-style-type: none"> <li>are allergic to the active substances or any of the other ingredients in this vaccine</li> <li>are currently suffering from an illness</li> <li>had serious encephalopathy (disease of brain) without an apparent cause within 7 days of a previous pertussis, tetanus or diphtheria vaccination</li> </ul> |
| <b>Things you should not do</b>    | <ul style="list-style-type: none"> <li>Do not have Adacel if you have a history of severe allergic reactions to any of the ingredients listed, previous dose of this vaccine or another vaccine designed to protect against pertussis, tetanus and diphtheria.</li> </ul>                                                                                                                                                   |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"> <li>Adacel is usually stored in the doctor's surgery or clinic. However, if you need to store Adacel keep it in the refrigerator, between 2°C and 8°C. Do not freeze Adacel. Freezing destroys the vaccine.</li> </ul>                                                                                                                                                                   |

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

### 6. Are there any side effects?

The most common side effects of Adacel are local reaction around the injection site, headaches, tiredness, fever, chills, soreness, joint pain, nausea and vomiting, diarrhoea, loss of appetite.

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.

# Adacel®

**Active ingredients:** *Diphtheria toxoid, Tetanus Toxoid, Pertactin, Pertussis filamentous haemagglutinin, Pertussis fimbriae 2 + 3, and Pertussis toxoid*

## Consumer Medicine Information (CMI)

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

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

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

## 1. Why am I using Adacel?

**Adacel contains the active ingredient Diphtheria toxoid, Tetanus toxoid, Pertactin, Pertussis filamentous haemagglutinin, Pertussis fimbriae 2 + 3, and Pertussis toxoid.**

Adacel is a vaccine used to help prevent whooping cough (pertussis), tetanus and diphtheria.

**This vaccine is for use as a booster in persons from the age of 10 years who have previously received childhood immunisation.** Use of Adacel 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.

Adacel is not intended for childhood immunisation.

The use of Adacel should be determined on the basis of official recommendations and by your doctor.

Whooping cough, tetanus and diphtheria cause significant sickness and sometimes death in unvaccinated infants, children, and adults.

Adacel works by causing the body to produce its own protection against whooping cough, tetanus, and diphtheria. 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. 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 any of these diseases.

The chance of a severe reaction from Adacel is very small, but the risks from not being vaccinated against these diseases may be very serious.

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

### Warnings

**Do not use Adacel if:**

- you are allergic to the active ingredients, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- a history of severe allergic reaction to a previous dose of this vaccine or another vaccine designed to protect against pertussis, tetanus and diphtheria. Symptoms of an allergic reaction may include:
  - o shortness of breath, wheezing or difficulty breathing
  - o swelling of the face, lips, tongue or other parts of the body
  - o skin rash, itching or hives
- had serious encephalopathy (disease of brain) without an apparent cause within 7 days of a previous pertussis, tetanus or diphtheria vaccination
- moderate or high temperature and/or acute illness

Adacel is not recommended for use in children under 10 years. If you are not sure whether you should have Adacel, talk to your doctor or pharmacist.

**Check with your doctor if you:**

- have a moderate or high temperature and/or acute illness. 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.
- you have, or have had, any medical conditions, especially the following:
  - o lowered immunity due to diseases such as some blood disorders, kidney disease requiring dialysis, HIV/AIDS or cancer
  - o lowered immunity due to treatment with medicines
  - o Guillain-Barre syndrome (temporary inflammation of nerves causing pain, paralysis and sensitivity disorders) after being given a vaccine containing tetanus toxoid (an inactivated form of tetanus toxin). In this case, the decision to give any further vaccine containing tetanus toxoid should be evaluated by your doctor.
  - o undiagnosed illness of the brain or epilepsy which is not controlled. Your doctor will assess the potential benefit offered by vaccination
  - o bleeding disorder
- have an allergy to latex

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 risk and benefits of having Adacel during pregnancy.

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

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

Your doctor will discuss the possible risks and benefits of having Adacel during breastfeeding.

### 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.

**Some medicines may interfere with Adacel and affect how it works.**

**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.**

#### Having other vaccines

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

### 4. How do I use Adacel?

#### How much to use

- The dose of Adacel is a single dose of 0.5mL
- Adacel is given as an injection, usually into your upper arm muscle by a doctor or nurse.
- Adacel should not be injected directly into the veins.

#### When to use Adacel

- Adacel is generally given whenever a booster dose of whooping cough, tetanus and diphtheria vaccine is required.

#### If you use too much Adacel

Overdose is most unlikely because your doctor or nurse gives the injections. If you have any concerns, ask your doctor.

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

#### Things you should do

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

- do not feel well after having Adacel

Remind any doctor, dentist or pharmacist you visit that you are using Adacel.

### Looking after your medicine

- Adacel is usually stored in the doctor's surgery or clinic, or at the pharmacy.
- However, if you need to store Adacel:
  - o Keep Adacel in the original pack until it is time for it to be given.
  - o Keep it in the refrigerator, between 2°C and 8°C. If Adacel happens to be stored out of the refrigerator at room temperature, it can be used for up to 72 hours after it was last refrigerated. If Adacel is stored out of the refrigerator for longer than 72 hours, it should be discarded.
  - o Do not freeze Adacel. Freezing destroys the vaccine.
  - o Do not use Adacel after the expiry date printed on the pack.
  - o Do not use Adacel 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.

Do not use this medicine after the expiry date.

### 6. Are there any side effects?

All vaccines 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 redness, pain or discomfort, swelling or the formation of hard lumps</li><li>• headaches</li><li>• tiredness, weakness or fatigue</li><li>• fever</li><li>• chills</li><li>• soreness, aching muscles, muscle tenderness or weakness (not caused by exercise)</li><li>• joint pain or joint swelling</li><li>• nausea and vomiting</li><li>• diarrhoea</li><li>• loss of appetite</li><li>• large injection site reactions and extensive limb swelling</li><li>• injection site bruising, abscess</li><li>• A small lump in the area where the vaccine was injected.</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>• sudden severe allergic reactions (anaphylactic reaction), for which symptoms may include rash, low blood pressure (hypotension), swelling of the face, lips, tongue or other parts of the body (angioedema, oedema), shortness of breath, wheezing or trouble breathing</li><li>• neurological disorders that may result in confusion, numbness or tingling, pain and weakness of the limbs, loss of balance, loss of reflexes, paralysis of parts or all the body (Guillain-Barre syndrome, brachial neuritis, myelitis)</li><li>• decreased feeling or sensitivity, especially in the skin (hypoesthesia)</li><li>• fainting</li><li>• convulsion</li><li>• drooping eyelid and sagging muscles on one side of the face (facial palsy)</li><li>• tingling or numbness of the hands or feet (paraesthesia)</li><li>• itching or hives on the skin (urticaria, pruritus)</li><li>• weakness, and pain in muscles (myositis)</li><li>• inflammation of heart muscle, for which symptoms may include shortness of breath, chest pain and irregular heartbeat (myocarditis)</li></ul> | <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> |

**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) in Australia or in New Zealand at <https://pophealth.my.site.com/carmreportnz/s/>.

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

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

## What Adacel contains

|                                                 |                                                                                                                                                                                                                                                                                                                                        |
|-------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Active ingredient (main ingredient)</b>      | <ul style="list-style-type: none"><li>• not less than 2 IU (2 Lf) diphtheria toxoid</li><li>• not less than 20 IU (5 Lf) tetanus toxoid</li><li>• 2.5 micrograms pertussis toxoid</li><li>• 5 micrograms pertussis filamentous haemagglutinin</li><li>• 3 micrograms pertactin</li><li>• 5 micrograms pertussis fimbriae 2+3</li></ul> |
| <b>Other ingredients (inactive ingredients)</b> | <ul style="list-style-type: none"><li>• aluminium phosphate</li><li>• phenoxyethanol</li><li>• formaldehyde</li><li>• glutaral</li><li>• water for injections</li></ul>                                                                                                                                                                |

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

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.

## What Adacel looks like

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

### AUST R number

297685 (syringe)

### Who distributes Adacel

Distributed in Australia by:

sanofi-aventis australia Pty Ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Freecall: 1800 818 806

Email: [medinfo.australia@sanofi.com](mailto:medinfo.australia@sanofi.com)

Distributed in New Zealand by:

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