

## 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 does my child need Tripacel?

Tripacel is a vaccine. It is used to prevent three diseases, diphtheria, tetanus and whooping cough (pertussis), in infants and children.

For more information, see Section [1. Why does my child need Tripacel?](#) in the full CMI.

### 2. What should I know before my child is given Tripacel?

Do not use if your child ever had an allergic reaction to Tripacel or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if your child has or has had any other medical conditions or is taking any other medicines.**

For more information, see Section [2. What should I know before my child is given Tripacel?](#) in the full CMI.

### 3. What if my child is taking other medicines?

Some medicines may interfere with Tripacel and affect how it works.

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

### 4. How Tripacel is given?

Tripacel is given by a doctor or nurse as an injection into muscle.

More instructions can be found in Section [4. How is Tripacel given?](#) in the full CMI.

### 5. What should I know after my child is given Tripacel?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• <b>Keep an updated record of your child's vaccinations.</b></li><li>• <b>Keep follow-up appointments with your doctor or clinic.</b></li></ul>
<b>Looking after your child's medicine</b>	Tripacel is usually stored in the doctor's surgery or clinic. However, if you need to store Tripacel: <ul style="list-style-type: none"><li>• keep in the fridge between 2-8°C. Do not freeze.</li></ul>

For more information, see Section [5. What should I know after my child is given Tripacel?](#) in the full CMI.

### 6. Are there any side effects?

- Common side effects include local reaction around the injection site, drowsiness, decreased activity, irritability, eating and drinking less than usual, crying more than usual, screaming, nausea, vomiting, diarrhoea, fever greater than 37°C, itching, rash. Serious side effects include sudden onset of signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, difficulty breathing or collapse.

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.

# Tripacel®

**Active ingredient(s):** *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 Tripacel. **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 Tripacel.**

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

- [1. Why does my child need Tripacel?](#)
- [2. What should I know before my child is given Tripacel?](#)
- [3. What if my child is taking other medicines?](#)
- [4. How Tripacel is given](#)
- [5. What should I know after my child is given Tripacel?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why does my child need Tripacel?

**Tripacel contains the active ingredients Diphtheria toxoid, Tetanus toxoid, Pertactin, Pertussis filamentous haemagglutinin, Pertussis fimbriae 2 + 3 and Pertussis toxoid.** Tripacel is a combination vaccine used to help prevent three diseases, diphtheria, tetanus and whooping cough (pertussis), in infants and children. These three diseases can each cause severe or life threatening illness in young children.

**This vaccine is for use in children up to 7 years of age, and is used in infants from the age of 2 months who are at the greatest risk from these diseases.**

#### How Tripacel works

Tripacel works by causing the body to produce its own protection against the bacteria (germs) which cause diphtheria, tetanus and whooping cough. The body makes substances (antibodies) which circulate in the blood and fight diphtheria, tetanus and pertussis germs.

It usually takes several weeks after the full course of vaccination to develop acceptable levels of protection against diphtheria, tetanus and pertussis.

Full protection requires a primary course providing 3 injections at recommended intervals. A fourth and fifth dose (follow-up, or booster doses) are also required.

Most children who receive all five doses will produce enough antibodies to protect against the diseases diphtheria, tetanus and pertussis. However, as with many vaccines, 100% protection cannot be guaranteed.

Tripacel cannot give your child the illnesses diphtheria, tetanus or whooping cough (pertussis).

### 2. What should I know before my child is given Tripacel?

#### Warnings

**Do not use Tripacel if your child:**

- is allergic to Diphtheria toxoid, Tetanus toxoid, Pertactin, Pertussis filamentous haemagglutinin, Pertussis fimbriae

2 + 3, Pertussis toxoid, or any of the ingredients listed at the end of this leaflet.

- is allergic to any other diphtheria, tetanus and/or pertussis vaccine.
- has an immediate severe allergic reaction to a previous dose of Tripacel or any other vaccine containing diphtheria, tetanus and/or pertussis.
- has an otherwise unidentifiable brain disorder within 7 days of a previous dose of Tripacel or any other diphtheria, tetanus and/or pertussis vaccine. Symptoms of severe, acute brain disorder include: prolonged seizure, fit or convulsion, prolonged unconsciousness, or an abnormality of the nervous system.
- has a progressive nervous system disorder such as infant spasm, uncontrolled epilepsy. The vaccination may be considered only after a treatment has been established and the condition is stabilised.
- has an illness with febrile or acute infection. The vaccination shall be postponed until after the child has recovered.

Always check the ingredients to make sure your child can receive this vaccine.

#### Check with your doctor if your child:

- has reacted to Tripacel or any other vaccine with any of the following:
  - severe allergic reaction.
  - fits or convulsions within three days.
  - within 2 days, shock-like state or unresponsiveness for a long period of time. Symptoms include shallow breathing, breathing which stops temporarily, skin pale when compared to normal healthy skin colour.
  - within 2 days, high temperature (greater than 40.5°C), without any other identifiable cause.
  - within 2 days, crying or screaming lasting for more than 3 hours.
- has or had any medical conditions, especially the following:
  - lowered immunity due to diseases (such as HIV/AIDS or cancer) or medicines used to treat cancer including radiation therapy.
  - bleeding disorder.
  - a higher risk of convulsion than the general population. A fever-reducing medication may be given to your child.
  - fainted with a previous injection. Fainting can occur following vaccination. Appropriate measures should be taken to prevent falling injury.

After vaccination, 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?](#)

### 3. What if my child is taking other medicines?

Tell your doctor or pharmacist if your child is taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

For age appropriate situations, Tripacel can be given at a separate injection site during the same visit with other vaccines.

Tell your doctor if your child has been treated with medicines that may affect the body's natural defences (immune system) such as high-dose corticosteroids or chemotherapy. Response to vaccines may not be optimal.

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

### 4. How Tripacel is given

#### How much to use

- Tripacel is given by a doctor or nurse as an injection into muscle.
- For infants under the age of 12 months, it is given as an injection into the upper thigh. In older children who have started walking, the vaccine is usually injected into the upper arm.

#### When to use Tripacel

- The primary immunisation schedule is one 0.5 mL dose given at 2, 4 and 6 months of age. A booster dose (0.5 mL) is usually given at 18 months of age. Another booster dose should be given when children are between 4 and 6 years of age (about the time of school entry).

#### If your child misses a dose of Tripacel

If your child misses a dose, talk to your doctor and arrange another visit as soon as possible.

#### If your child received too much Tripacel

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 after my child is given Tripacel?

#### Things you should do

- Keep an updated record of your child's vaccinations.
- Keep follow-up appointments with your doctor or clinic.

It is important your child has all follow-up doses of Tripacel at the appropriate times to make sure the vaccine has the best chance of providing protection against diphtheria, tetanus and whooping cough (pertussis).

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

- does not feel well after having Tripacel

Remind any doctor, dentist or pharmacist you visit that your child had Tripacel.

### Looking after your child's medicine

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

- keep Tripacel where children cannot reach it.
- keep Tripacel in the original pack until it is time for it to be given.
- keep Tripacel in the refrigerator, at 2° to 8°C. DO NOT FREEZE Tripacel. Freezing destroys the vaccine.

### Getting rid of any unwanted medicine

If your child no longer needs to use this vaccine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this vaccine after the expiry date.

### 6. Are there any side effects?

All medicines including vaccines can have side effects. If your child experiences 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, tenderness, swelling, rash, whole thigh or upper arm swelling</li> <li>• drowsiness</li> <li>• decreased activity</li> <li>• irritability, fussiness</li> <li>• eating and drinking less than usual</li> <li>• crying more than usual</li> <li>• screaming</li> <li>• nausea, vomiting</li> <li>• diarrhoea</li> <li>• fever greater than 37°C</li> <li>• itching, rash.</li> </ul>	<p><b>Speak to your doctor if your child has any of these less serious side effects and they worry you.</b></p>

#### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• sudden onset of signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, difficulty breathing or collapse.</li> <li>• swollen glands in the neck, armpit or groin</li> <li>• abscess or infection at the injection site</li> <li>• shock-like state or prolonged unresponsiveness.</li> <li>• convulsions with or without high temperature</li> <li>• pale skin or bluish appearance to finger nails or lips</li> <li>• unusual muscle slackness</li> <li>• fainting</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>

**Tell your doctor or pharmacist if you notice anything else that may be making your child feel unwell.**

Other side effects not listed here may occur in some children.

### Reporting side effects

After you have received medical advice for any side effects your child experienced, 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 vaccine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop giving any medicines to your child.**

## 7. Product details

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

### What Tripacel contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>• 10 micrograms pertussis toxoid</li><li>• 5 micrograms pertussis filamentous haemagglutinin</li><li>• 5 micrograms pertussis fimbriae 2 + 3</li><li>• 3 micrograms pertactin</li><li>• # 30IU (15 Lf) diphtheria toxoid</li><li>• # 40IU (5 Lf) tetanus toxoid</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• aluminium phosphate</li><li>• phenoxyethanol</li><li>• water for injections</li></ul> <p>Tripacel may also contain traces of the following:</p> <ul style="list-style-type: none"><li>• formaldehyde</li><li>• glutaral</li></ul>
<b>Potential allergens</b>	No

The manufacture of this product includes exposure to bovine derive 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.

**Your child should not receive this vaccine if they are allergic to any of these ingredients.**

### What Tripacel looks like

Tripacel is a white to off-white cloudy suspension for injection. Tripacel is contained in a single-dose 0.5 mL glass container (vial).

AUST R 63120

### Who distributes Tripacel

#### Australia:

sanofi-aventis australia Pty Ltd

12 – 24 Talavera Road

Macquarie Park NSW 2113

Australia

Tel: 1800 818 806

#### New Zealand:

sanofi-aventis new zealand limited

Level 8, 56 Cawley St

Ellerslie, Auckland

New Zealand

Tel: 0800 283 684

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