

Tripacel®

Pertussis Vaccine-Acellular, Combined with Diphtheria and Tetanus Toxoids (Adsorbed)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tripacel.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of your child having Tripacel against the benefits they expect it will have.

If you have any concerns about this vaccine, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may need to read it again.

What Tripacel is used for

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 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).

Before you are given Tripacel

When your child must not be given Tripacel

Do not give Tripacel to a child who has an allergy to:

- Tripacel or any of the ingredients listed at the end of this leaflet,
- any other diphtheria, tetanus and/or pertussis vaccine.

Do not give Tripacel to a child who has, or has had, any of the following medical conditions:

- an immediate severe allergic reaction to a previous dose of Tripacel or any other vaccine

containing diphtheria, tetanus and/or pertussis vaccine.

- 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.
- 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.
- an illness with febrile or acute infection. The vaccination shall be postponed until after the child has recovered.

Do not use Tripacel after the expiry date printed on the pack.

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

If you are not sure whether your child should have Tripacel, talk to your doctor or pharmacist.

Before your child is given Tripacel

Tell 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.

Tell your doctor if your child has or has 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.

Tell your doctor if your child has allergies to:

- any other medicines.
- any other substances, such as foods, preservatives or dyes.

Taking other medicines

Tell your doctor or pharmacist if your child is taking or has recently taken any other medicines, including medicines obtained without prescription.

Having other vaccines

Tell your doctor if your child has had any vaccines in the previous 4 weeks.

Your doctor will advise you if Tripacel is to be given at the same visit as another vaccine.

How Tripacel is given

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.

How much is given and when it is given

The primary immunisation schedule is one 0.5mL 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

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

After having Tripacel

Things you must 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).

Side effects

Tell your doctor or pharmacist as soon as possible if your child does not feel well after having Tripacel.

Tripacel may have unwanted side effects in a few people. All

medicines, including vaccines, can have side effects. Sometimes they are serious, most of the time they are not. Your child may need medical treatment if he/she gets some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Allergic reaction

As with all vaccines given by injection, there is a very small risk of a severe allergic reaction.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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.

These are very serious side effects. If your child has them, your child may have had a severe allergic reaction to Tripacel. Your child needs urgent medical attention or hospitalisation. Mostly this type of side effect occurs within the first few hours of vaccination.

The following are the more common side effects of Tripacel. Mostly they are mild and short-lived.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- local reaction around the injection site such as redness, tenderness, swelling, rash, whole thigh or upper arm swelling
- drowsiness
- decreased activity
- irritability, fussiness
- eating and drinking less than usual
- crying more than usual
- screaming
- nausea, vomiting
- diarrhoea

- fever greater than 37°C
- itching, rash.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swollen glands in the neck, armpit or groin
- abscess or infection at the injection site
- shock-like state or prolonged unresponsiveness.
- convulsions with or without high temperature
- pale skin or bluish appearance to finger nails or lips
- unusual muscle slackness
- fainting

All of these side effects are very rare.

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

Tell your doctor or pharmacist if you notice anything that is making your child feel unwell.

Do not be alarmed by this list of possible side effects.

Your child may not experience any of them.

Storing Tripacel

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.

Product description

Tripacel is contained in a single-dose 0.5 mL glass container (vial).

What Tripacel looks like

Tripacel is a white to off-white cloudy suspension for injection.

Ingredients

Active ingredients:

- 10 micrograms pertussis toxoid
- 5 micrograms pertussis filamentous haemagglutinin
- 5 micrograms pertussis fimbriae 2 + 3
- 3 micrograms pertussis
- ≥30IU (15 Lf) diphtheria toxoid
- ≥40IU (5 Lf) tetanus toxoid

Other ingredients:

- aluminium phosphate
- phenoxyethanol
- water for injections
- residual formaldehyde
- residual glutaral

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.

Distributor

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

AUST R Number

AUST R 63120

Date of Preparation

23 March 2020

tripacel-ccds5-cmiv3-23mar20