

ADACEL®

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 ADACEL®.

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 you having ADACEL® 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 ADACEL® is used for

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.

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.

How it works

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.

A course of whooping cough, tetanus and diphtheria vaccine is usually given during early childhood at 2, 4 and 6 months of age, followed by a booster at 4 years of age. In case of whooping cough, tetanus and diphtheria, a second booster is required at the age of 15-17 years.

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.

Before you are given ADACEL®

When you must not be given it

Do not have ADACEL® if you have an allergy to:

- ADACEL® or any of the ingredients listed at the end of this leaflet
- had an anaphylactic or other allergic reaction to a previous dose of this vaccine or another vaccine designed to protect against pertussis, tetanus and diphtheria
- had serious encephalopathy (disease of brain) without an apparent cause within 7 days of a previous pertussis, tetanus or diphtheria vaccination
- any vaccines

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives

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.

Before you are given it

Tell your doctor if you have 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

Tell your doctor if you have not previously received the complete course of tetanus and diphtheria vaccination.

Tell your doctor if you have 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.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- lowered immunity due to diseases such as some blood disorders, malaria, kidney disease requiring dialysis, HIV/AIDS or cancer
- lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy)
- leukaemia or any other cancers of the blood, bone marrow or lymph system
- brain disease
- epilepsy
- fits or convulsions
- severe allergic reactions
- a low blood platelet count

Tell your doctor if you have allergies to:

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

Tell 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.

Tell your doctor if you are breast-feeding.

Your doctor will discuss the possible risks and benefits of having ADACEL® during breast-feeding.

Taking other medicines

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

Having other vaccines

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

How ADACEL® is given

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

For some people with bleeding problems, ADACEL® may need to be given under the skin.

ADACEL® should not be injected directly into the veins.

How much is given

The dose of ADACEL® is a single dose of 0.5mL.

When it is given

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after having ADACEL®.

ADACEL® 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. You may need medical treatment if you get some of the side effects.

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

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, pain or discomfort, swelling or the formation of hard lumps
- headaches
- tiredness, weakness or fatigue
- fever
- chills
- soreness, aching muscles, muscle tenderness or weakness (not caused by exercise)
- joint pain or joint swelling
- nausea and vomiting
- diarrhoea
- loss of appetite

Mostly these are mild and short-lived. If however, these symptoms persist, then you should tell your doctor.

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

- sudden severe allergic reactions (anaphylactic reaction), for which symptoms may include rash, itching or hives on the skin (urticaria, pruritus), 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

- 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)
- decreased feeling or sensitivity, especially in the skin (hypoesthesia)
- weakness, and pain in muscles (myositis)
- fainting
- convulsion
- drooping eyelid and sagging muscles on one side of the face (facial palsy)
- tingling or numbness of the hands or feet (paraesthesia)

These are very serious side effects. You may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

You may not experience any of them.

After using ADACEL®

Storage

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

- Keep it where children cannot reach it.
- Keep ADACEL® in the original pack until it is time for it to be given.
- Keep it in the refrigerator, between 2°C and 8°C. Do not freeze ADACEL®. Freezing destroys the vaccine.

Do not use ADACEL® after the expiry date printed on the pack.

Do not use ADACEL® if the packaging is torn or shows signs of tampering

Product description

What it looks like

ADACEL® is a sterile, uniform, cloudy, white suspension for injection.

Ingredients

Active ingredients:

- 2.5 mcg pertussis toxoid
- 5 mcg pertussis filamentous haemagglutinin
- 5 mcg pertussis fimbriae types 2 and 3
- 3 mcg pertussis pertactin
- 2 or more IU diphtheria toxoid
- 20 or more IU tetanus toxoid

Other ingredients:

- aluminium phosphate
- phenoxyethanol
- formaldehyde
- glutaraldehyde
- water for injections

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.

Name and address of the sponsor

Australia:

sanofi-aventis australia Pty Ltd

Talavera Corporate Centre - Building D

12 - 24 Talavera Road

Macquarie Park NSW 2113

Australia

Tel: 1800 829 468

New Zealand:

sanofi-aventis new zealand limited

Level 8, James & Wells Tower

56 Cawley St

Ellerslie

Auckland

New Zealand

Tel: 0800 727 838

Aust R number

Aust R 106554

Date of preparation

25 March 2013