

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.

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.

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.

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:

- a history of severe allergic reaction to any of the ingredients listed at the end of this leaflet
- a history of severe 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
- moderate or high temperature and/or acute illness

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 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.

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, kidney disease requiring dialysis, HIV/AIDS or cancer
- lowered immunity due to treatment with medicines
- 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.
- undiagnosed illness of the brain or epilepsy which is not controlled. Your doctor will assess the potential benefit offered by vaccination
- bleeding disorder

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.

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

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.

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
- large injection site reactions and extensive limb swelling
- injection site bruising, abscess

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, 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)
- fainting
- convulsion
- drooping eyelid and sagging muscles on one side of the face (facial palsy)
- tingling or numbness of the hands or feet (paraesthesia)
- itching or hives on the skin (urticaria, pruritus)
- weakness, and pain in muscles (myositis)
- inflammation of heart muscle, for which symptoms may include shortness of breath, chest pain and irregular heartbeat (myocarditis)

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:

- not less than 2 IU (2 Lf) diphtheria toxoid
- not less than 20 IU (5 Lf) tetanus toxoid
- 2.5 micrograms pertussis toxoid
- 5 micrograms pertussis filamentous haemagglutinin
- 3 micrograms pertactin
- 5 micrograms pertussis fimbriae 2+3

Other ingredients:

- aluminium phosphate
- phenoxyethanol
- formaldehyde
- glutaral
- 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

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