

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 or your child 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 or your child 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 or your child is given ADACEL[®]

When you or your child must not be given it

Do not have ADACEL[®] if you or your child has 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.

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.

If you are not sure whether you or your child should have ADACEL[®], talk to your doctor or pharmacist.

Before you or your child is given it

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

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

Having other vaccines

Tell your doctor if you or your child has had any vaccines in the last 4 weeks.

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

Your doctor and pharmacist may have more information on medicines and vaccines to be careful with or avoid during vaccination with ADACEL[®].

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 0.5 mL.

When it is given

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

After having ADACEL[®]

Things you or your child must do

Keep an updated record of your vaccinations.

Things to be careful of

Be careful driving or operating machinery until you know how ADACEL[®] affects you.

ADACEL[®] should not normally interfere with your ability to drive or operate machinery. However, it may cause tiredness, drowsiness in some people.

Side effects

Tell your doctor or pharmacist as soon as possible if you or your child does 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 or your child 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, itchiness, tenderness, pain or discomfort, warmth, burning or stinging, swelling or the formation of hard lumps or scars
- flushing or redness of the skin
- 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

These are the more common side effects of ADACEL[®]. Mostly these are mild and short-lived. If however, these symptoms persist for more than 1 week, then you should tell your doctor.

Tell your doctor immediately if you notice any of the following:

- high fever (>40.5°C)
- unusual high-pitched or inconsolable crying
- severe dizziness, unsteadiness when walking or spinning sensation
- fits or convulsions
- abscess at the injection site
- unusual bleeding, bruising or purple spots on the skin
- skin rash, itchy spots or red lumps on the skin
- itchiness, hives or rash over the body
- painful, swollen joints

These may be serious side effects. You or your child may need urgent medical attention. Serious side effects are rare.

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

- sudden signs of allergy such as red, itchy rash or hives, swelling of the face, lips, tongue or other parts of the body
- swelling of the whole arm or leg
- shortness of breath, wheezing or trouble breathing
- unusual stiffness causing loss of movement
- a seizure or convulsion, which may be accompanied by a very high temperature
- feeling weak or paralysed, or generally feeling sore or tender
- rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting (shock)
- headache and high temperature associated with hallucinations, confusion, paralysis of part or all of the body, disturbances of behaviour, speech and eye movements, stiff neck and sensitivity to light

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

All of these side effects are 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 or your child feel unwell.

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

You or your child may not experience any of them.

Storing ADACEL[®]

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.

Product description

What it looks like

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

Ingredients

Active ingredients:

- 2.5µg pertussis toxoid
- 5µg pertussis filamentous haemagglutinin
- 5µg pertussis fimbriae types 2 and 3
- 3µg pertussis pertactin
- ≥ 2 IU diphtheria toxoid
- ≥ 20 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.

Manufacturer

Sanofi Pasteur Limited
Toronto, Ontario, Canada

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