

ADACEL[®] POLIO

Pertussis Vaccine – Acellular and Diphtheria and Tetanus Toxoids (Adsorbed) Combined with Inactivated Poliovirus Type 1,2 and 3 (Vero cell)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ADACEL POLIO.

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 POLIO 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 POLIO is used for

ADACEL POLIO is a vaccine used to help prevent whooping cough (pertussis), tetanus, diphtheria and polio.

This vaccine is for use as a booster in adults, adolescents and children aged four years and older who have previously received childhood immunisation.

Children from four to six years of age should have already received four doses of whooping cough, tetanus, diphtheria and polio vaccine.

ADACEL POLIO is not intended for primary immunisation.

The use of ADACEL POLIO should be determined on the basis of official recommendations and by your doctor.

Polio, whooping cough, tetanus and diphtheria cause significant sickness and sometimes death in unvaccinated infants, children, and adults.

How it works

ADACEL POLIO works by causing the body to produce its own protection against whooping cough, tetanus, diphtheria, and polio. 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, diphtheria and polio 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 POLIO 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 POLIO

When you or your child must not be given it

Do not have ADACEL POLIO if you or your child has an allergy to:

- ADACEL POLIO 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, diphtheria or polio.
- 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 POLIO is not recommended for use in children under 4 years.

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

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

If you are not sure whether you or your child should have ADACEL POLIO, 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 POLIO during pregnancy.

Tell your doctor if you are breast-feeding.

Your doctor will discuss the possible risks and benefits of having ADACEL POLIO 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 POLIO 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 POLIO.

How ADACEL POLIO is given

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

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

ADACEL POLIO should not be injected directly into the veins

How much is given

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

When it is given

ADACEL POLIO is generally given whenever a booster dose of tetanus and diphtheria is required and where a booster dose of whooping cough and polio is considered necessary.

After having ADACEL POLIO

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 POLIO affects you.

ADACEL POLIO should not normally interfere with your ability to drive or operate machinery. However, it may cause light-headedness, 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 POLIO.

ADACEL POLIO 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 bruising, 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
- rash
- headaches
- tiredness, weakness or fatigue
- fever
- rigors
- soreness, aching muscles, muscle tenderness or weakness (not caused by exercise)
- joint pain or joint swelling
- irritability
- nausea and vomiting
- diarrhoea

These are the more common side effects of ADACEL POLIO. 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 convulsion
- 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 POLIO

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

- **Keep it where children cannot reach it.**
- **Keep ADACEL POLIO 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 POLIO.** Freezing destroys the vaccine.

Product description

What it looks like

ADACEL POLIO 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 IU diphtheria toxoid

- ≥ 20 IU tetanus toxoid
- 40 DAgU Poliovirus inactivated type 1
- 8 DAgU Poliovirus inactivated type 2
- 32 DAgU Poliovirus inactivated type 3

Other ingredients

- aluminium phosphate
- phenoxyethanol
- polymyxin B sulfate
- neomycin
- streptomycin
- formaldehyde
- glutaraldehyde
- polysorbate 80
- 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

Distributor

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Aust R number

Aust R 106565 – Vial
Aust R 106576 - Syringe

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