

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ADACEL[®]-POLIO

Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed Combined with Inactivated Poliomyelitis Vaccine

Read this carefully before you receive ADACEL[®]-POLIO. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about ADACEL[®]-POLIO.

What is ADACEL[®]-POLIO used for?

ADACEL[®]-POLIO is a vaccine that is used to boost the body's protection against tetanus, diphtheria, pertussis (whooping cough) and poliomyelitis. This vaccine may be given to children, adolescents and adults from the age of 4 and above.

The majority of people who are vaccinated with ADACEL[®]-POLIO will produce enough antibodies to protect them against these 4 diseases. However, as with all vaccines, 100% protection cannot be guaranteed.

ADACEL[®]-POLIO may be given to a pregnant woman to help protect her baby against whooping cough.

How does ADACEL[®]-POLIO work?

ADACEL[®]-POLIO causes your body to produce its own natural protection against tetanus, diphtheria, pertussis and polio viruses. After you receive the vaccine, your body begins to make substances called antibodies. Antibodies help your body to fight disease. If a vaccinated person comes into contact with one of the germs that cause these diseases, the body is usually ready to destroy it.

What are the ingredients in ADACEL[®]-POLIO?

Medicinal ingredients (each 0.5 mL dose): tetanus toxoid, diphtheria toxoid, pertussis toxoid, filamentous haemagglutinin, pertactin, fimbriae types 2 and 3, and killed, purified viruses from three strains of poliomyelitis viruses.

Non-medicinal ingredients: Aluminum phosphate, 2-phenoxyethanol, ethanol, polysorbate 80. Formaldehyde, glutaraldehyde, calf serum protein, neomycin, polymyxin B and streptomycin are present in trace amounts.

ADACEL[®]-POLIO comes in the following dosage forms:

ADACEL[®]-POLIO is a liquid vaccine that is injected into a muscle. A single dose is 0.5 mL.

Do not give ADACEL[®]-POLIO to:

- Persons who are known to have a severe allergy to any ingredient in the vaccine or its container, or who have had a severe allergic reaction after receiving a vaccine that contained similar ingredients.
- Persons who have had a serious nervous system disorder within 7 days after a previous pertussis vaccine.

To help avoid side effects and ensure proper use, talk to your healthcare professional **BEFORE** you or your child receive ADACEL®-POLIO if you or your child have, or have had any of the following conditions:

- **A high fever or serious illness.** Delay the vaccination until the person is better.
- **An allergy to any component of the vaccine or the container.**
- **A serious nervous system adverse event (Guillain-Barré syndrome or brachial neuritis) following a previous tetanus vaccination.**
- **A progressive nervous system disorder** or uncontrolled epilepsy, vaccination may be considered only after a treatment has been established.
- **Pregnant women or nursing mothers.** It is important that you understand the risks and benefits of vaccination. Tell the person giving you the injection if you are pregnant or breast-feeding. The health care professional will recommend whether you should receive ADACEL®-POLIO.
- **A weakened immune system.** The vaccine may provide you with a lower level of protection than it does for people with healthy immune systems. If possible, try to postpone the vaccination until after you have completed the treatment that affects your immune system.
- **A bleeding disorders or taking blood-thinning medications.** Tell the person giving you the injection about your condition. The injection must be done carefully to prevent excessive bleeding.
- **Fainted with a previous injection.** Fainting can occur following vaccination. Appropriate measures should be taken to prevent falling injury.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ADACEL®-POLIO:

Do not mix ADACEL®-POLIO with other vaccines or medicinal products in the same syringe.

ADACEL®-POLIO may be given at the same time, but at separate sites with:

- Inactivated Flu vaccine
- Hepatitis B vaccine.

Usual dose:

For persons 4 years of age and above who have previously been immunized against tetanus, diphtheria, pertussis and poliomyelitis, the recommended single dose is 0.5 mL.

The vaccination should be given in the muscle, preferably in the deltoid (shoulder) region.

Overdose:

If you think you, or a person you are caring for, have taken too much ADACEL®-POLIO, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Not applicable to this vaccine.

What are possible side effects from using ADACEL[®]-POLIO?

These are not all the possible side effects you may have when taking ADACEL[®]-POLIO. If you experience any side effects not listed here, tell your healthcare professional.

A vaccine, like any medicine, may cause serious problems, such as severe allergic reactions. The risk of ADACEL[®]-POLIO causing serious harm is extremely small. The small risks associated with ADACEL[®]-POLIO are much less than the risks associated with getting the diseases.

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well after receiving ADACEL[®]-POLIO.

Serious side effects are extremely rare.

Some people who receive ADACEL[®]-POLIO may have mild side effects such as redness, swelling or pain at the site of the injection. They may also feel tired, or have a headache, generalized body ache and sore or swollen joints. These side effects usually go away within a few days.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Sanofi Pasteur Limited cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/ae-fi-essi-form-eng.php>) and send it to your local Health Unit.

Storage:

Store the vaccine in a refrigerator at 2° to 8°C (35° to 46°F). **Do not freeze.** Throw the product away if it has been exposed to freezing.

Do not use vaccine after the expiration date.

Keep out of reach of children.

If you want more information about ADACEL®-POLIO:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.sanofi.ca, or by calling 1-888-621-1146.

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