

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

#### **ADACEL®**

#### **Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed**

Read this carefully before you receive **ADACEL®**. This leaflet is a summary and will not tell you everything about **ADACEL®**. Talk to your doctor or pharmacist if you have any questions about this vaccine.

#### **What is ADACEL® used for?**

ADACEL® is a vaccine that is used to boost the body's protection against tetanus, diphtheria, and pertussis (whooping cough). This vaccine may be given to children, adolescents and adults 4 years of age and older. ADACEL® may be used as an alternative to the usual paediatric vaccine in children 4 to 6 years of age who are due for their pre-school booster against diphtheria, tetanus and pertussis. These children should also receive a separate booster with inactivated polio vaccine, when a polio booster is routinely recommended for this age group.

The majority of persons who are vaccinated with ADACEL® will produce enough antibodies to protect them against these 3 diseases. However, as with all vaccines, 100% protection cannot be guaranteed.

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

#### **How does ADACEL® work?**

ADACEL® causes your body to produce its own natural protection against tetanus, diphtheria and pertussis (whooping cough). 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®?**

Medicinal ingredients: tetanus toxoid, diphtheria toxoid, pertussis toxoid, filamentous haemagglutinin, pertactin and fimbriae types 2 and 3.

Non-medicinal ingredients: Aluminum phosphate, 2-phenoxyethanol. Residual formaldehyde and glutaraldehyde are present in trace amounts.

#### **ADACEL® comes in the following dosage forms:**

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

**Do not use ADACEL® if:**

- You are known to have a severe allergy to any ingredient in the vaccine or its container, or have had a severe allergic reaction after receiving a vaccine that contained similar ingredients.
- You 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 take ADACEL®. Talk about any health conditions or problems you may have, including:**

- **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 following a previous tetanus vaccination.**
- **A progressive nervous system disorder or uncontrolled epilepsy.** Vaccination may be considered only after a treatment has been established and the condition is stabilized.
- **Pregnant 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®.
- **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 disorder 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.
- **Have 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®:**

DO NOT mix ADACEL® with other vaccines or medicinal products in the same syringe.

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

- inactivated influenza vaccine
- hepatitis B vaccine

**How to take ADACEL®:**

**Usual dose:**

For persons aged 4 years of age and older – recommended 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®, 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®?**

These are not all the possible side effects you may have when taking ADACEL®. 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® causing serious harm is extremely small. The small risks associated with ADACEL® are much less than the risks associated with getting the diseases.

Serious side effects are extremely rare.

Some people who receive ADACEL® 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.

Uncommonly, a small lump in the area where the vaccine was injected may develop.

| Serious side effects and what to do about them   |                                      |              |
|--|--------------------------------------|--------------|
| Symptom / effect   | Talk to your healthcare professional |              |
|  | Only if severe                       | In all cases |
| <b>Anaphylaxis and Hypersensitivity:</b> severe allergic reaction with symptoms that can include: angioedema, edema, rash, hypotension |                                      | ✓            |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to 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 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 after the expiration date.

Keep out of reach and sight of children.

### **If you want more information about ADACEL®:**

- 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 Sanofi Canada website ([www.sanofi.ca](http://www.sanofi.ca)) or by contacting the vaccine producer, Sanofi Pasteur Limited, at 1-888-621-1146 (no charge).

This leaflet was prepared by Sanofi Pasteur Limited.

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