

## Patient Information

### ADACEL®

## Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed Rx only

### What is in this leaflet?

This leaflet provides information and answers common questions consumers may have about ADACEL vaccine. It is not intended to take the place of talking with your health-care professional. Rather, it is meant to inform you so that together you can make the best possible choices concerning your health. Vaccines, like all other medicines, have risks and benefits. Together with your health-care professional, you should consider this as well as other important information concerning ADACEL vaccine.

### What is ADACEL vaccine and what does it do?

ADACEL vaccine is meant to protect adolescents and adults from tetanus, diphtheria, and pertussis. It allows the body to produce enough antibodies so as to provide a defense against these three diseases. The vaccine can in no way cause any of these diseases to occur.

- **Tetanus** is also known as “lockjaw” because it causes severe inflexibility and spasms in the skeletal muscles. It can cause the jaw and neck muscles to tighten to the point where a person cannot open his or her mouth or swallow. Immunity to this disease does not occur naturally in the United States so it is important that this vaccine be given in order to protect all age groups.

- **Diphtheria** is generally linked with severe or fatal respiratory infections but can also, in critical cases, cause inflammation in the heart and nervous system. This disease can cause serious damage to the respiratory and nervous systems even to the point of death.

- **Pertussis**, commonly called “whooping cough,” affects the respiratory tract causing excessive coughing fits that can disturb normal breathing. This disease might at first seem to be a regular cold but can last for weeks or months without a health-care professional realizing that the symptoms are due to pertussis.

### Who should receive ADACEL vaccine?

- ADACEL vaccine is intended for both adolescents and adults 11 through 64 years of age.

### Who should not receive ADACEL vaccine?

- ADACEL vaccine should not be administered to anyone under 11 years of age or above 64 years of age.
- Persons who have had allergic reactions to a previous tetanus, diphtheria, or pertussis vaccination should not get ADACEL vaccine.

### When should extra care be used?

The health-care professional should make sure the benefits outweigh the risks when recommending ADACEL vaccine for:

- Persons with a bleeding disorder (ie, hemophilia or thrombocytopenia) because they might develop hematoma (serious bruise or collection of blood) where the vaccine is injected.
- Women who are pregnant or nursing.

Manufactured by:  
Sanofi Pasteur Limited  
Toronto Ontario Canada  
R1-0106

Distributed by:  
Sanofi Pasteur Inc.  
Swiftwater PA 18370 USA

### How is ADACEL vaccine administered?

A single dose of ADACEL vaccine is injected into the muscle of the upper arm of persons 11 through 64 years of age. Five years should have passed since the last tetanus, diphtheria, or pertussis vaccine.

It should be noted that clinical studies have been conducted to show that ADACEL vaccine is safe when given at the same time as hepatitis B vaccine or the flu vaccine.

### You should tell your health-care professional if you or your child:

- Has experienced after a previous pertussis vaccination any of the following:
  - Temperature of 105°F (40.5°C) or higher within 48 hours of vaccination
  - Collapse in shock-like state within 48 hours
  - Persistent and inconsolable crying lasting 3 hours or more, occurring within 48 hours
  - Seizures with or without fever occurring within 3 days
- Has experienced Arthus-type hypersensitivity reactions following a prior tetanus vaccine.
- Developed Guillain-Barré syndrome within 6 weeks following a prior tetanus vaccination.
- Has a central nervous system disorder, whether it is stable or not.
- Is a pregnant or nursing mother.

This information should not take the place of talking with your health-care professional about ADACEL vaccine.

### What are the possible side effects of ADACEL vaccine?

While side effects from vaccine administration are always possible, people receiving ADACEL vaccine may not experience any side effects at all. In general, ADACEL vaccine was associated with side effects that were similar to those common to standard tetanus-diphtheria vaccine. Pain at the injection site and low fever were reported more frequently in adolescents who received ADACEL vaccine than those who received tetanus-diphtheria vaccine.

The most common local side effects with ADACEL vaccine were injection site pain, redness, and swelling. Systemic side effects include headache, body aches, tiredness, and fever. These effects usually clear up within a few days. If events continue or become severe, tell your doctor. Other adverse events are possible. Please consult with your doctor.

### What ingredients are present in ADACEL vaccine?

ADACEL vaccine contains noninfectious tetanus, diphtheria, and pertussis proteins. Small amounts of aluminum phosphate, formaldehyde, glutaraldehyde, and 2-phenoxethanol are also present in each dose.

For more information about ADACEL vaccine, talk to your health-care professional. You may also visit [www.ADACELVACCINE.com](http://www.ADACELVACCINE.com).

This information is based on the ADACEL full Prescribing Information dated January 2006.

**SANOFI PASTEUR**