

Patient Information



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

What is in this Patient Information Sheet?

This sheet 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 help protect adults and adolescents from tetanus, diphtheria, and pertussis. The vaccine causes the body to produce antibodies (protection) against these 3 diseases. The vaccine cannot cause tetanus, diphtheria, or pertussis.

- **Tetanus:** Tetanus, also known as “lockjaw,” is an acute and often fatal disease caused by an extremely strong toxin produced by the tetanus bacteria. The toxin can cause severe inflexibility and painful spasms in the skeletal muscles. For example, the jaw and neck muscles can tighten to the point where a person cannot open his or her mouth or swallow. Spores of tetanus bacteria are present in soil everywhere and can get into the body via broken skin, for example a puncture wound. Immunization with tetanus vaccine is a way to help prevent the disease. Following childhood immunization, booster vaccinations should be given every 10 years.
- **Diphtheria:** Diphtheria bacteria can cause a respiratory or skin infection. Some strains of this bacterium produce a powerful toxin that may cause severe complications, affecting the heart and nervous system, and may even result in death. Complete immunization significantly reduces the risk of developing diphtheria and immunized persons who develop the disease have milder illness. Following childhood immunization, booster vaccinations should be given every 10 years.
- **Pertussis:** Pertussis is commonly called “whooping cough.” It 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 licensed as a single booster for both adolescents and adults 11 through 64 years of age. Five years should have passed since the last tetanus, diphtheria, or pertussis vaccine.

Who should not receive Adacel vaccine?

- Adacel vaccine has not been studied in individuals younger than 11 years or older than 64 years of age, and therefore should not be given to people in these age groups.
- Persons who had a severe allergic reaction to a previous tetanus, diphtheria, or pertussis vaccination should not get Adacel vaccine.
- Persons diagnosed with a brain disorder within 7 days after previously receiving a pertussis-containing vaccine.

How is Adacel vaccine given?

A single dose of Adacel vaccine is injected into the muscle of the upper arm. It should be noted that clinical studies have been done to show that Adacel vaccine is safe when given at the same time as hepatitis B vaccine or the flu vaccine.

What should I tell my health-care professional before I or my child receive Adacel vaccine?

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

- Has experienced severe injection site pain or swelling following a prior tetanus vaccine.
- Experienced Guillain-Barré syndrome (severe muscle weakness) or a severe brain disorder within 6 weeks following a prior tetanus vaccination.
- Has a brain disorder, whether it is stable or not.

Your health-care professional should discuss the potential benefits and risks of recommending Adacel vaccine, particularly for women who are pregnant or nursing.

- If you were vaccinated during pregnancy or if pregnant, ask your health-care professional about the sanofi pasteur vaccination pregnancy registry.

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?

Side effects to Adacel vaccine include injection site pain, redness, and swelling; headache, body ache, tiredness, and fever. Tell your doctor if you have ever experienced a severe brain disorder, such as encephalopathy (altered consciousness) or Guillain-Barré syndrome (severe muscle weakness), after a previous dose of a tetanus toxoid- or pertussis-containing vaccine. Other side effects may occur. As with any vaccine, there is a small risk of allergic reactions. Some signs of allergic reactions are hives, swelling of the throat, low blood pressure, shock, and difficulty breathing. If you begin to experience any of these signs seek treatment right away. These reactions are rare and usually occur before leaving the doctor's office. If you notice any other problems or symptoms following vaccination, please contact your health-care professional promptly. Vaccination with Adacel vaccine may not protect all people receiving the vaccine.

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-phenoxyethanol are also present in each dose.

For more information about Adacel vaccine, talk to your health-care professional. You may also visit VaccinePlace.com®.

This information is based on the Adacel vaccine full Prescribing Information dated January 2009.

Manufactured by:
Sanofi Pasteur Limited
Toronto Ontario Canada

R5-0109 USA
5751

Distributed by:
Sanofi Pasteur Inc.
Swiftwater PA 18370 USA

sanofi pasteur