

What all moms should know about protecting themselves and their children against pertussis

CALLING ALL NEW MOMS



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CALLING ALL NEW MOMS

Pertussis—a serious disease that every parent and person in close contact with infants should know about

As a mother, father, family member, or other caregiver, it is important to understand the role proper immunization plays in protecting you and the infants in your life from pertussis. Reported cases of pertussis, commonly known as whooping cough, are on the rise. It is the only disease against which we routinely vaccinate children that appears to be rising. Research has shown that immunity to this easily transmitted disease begins to wear off by early adolescence, leaving people susceptible to infection.

This brochure has been designed to give you the information you need to protect your family from pertussis. Please take time to read it and feel free to ask your or your children's health-care professional whether a pertussis booster vaccine is right for you.



Pertussis is a highly contagious disease¹

Symptoms of pertussis may include¹:

- Runny nose
- Severe cough that can make breathing difficult
 - Cough can last up to 8 weeks or longer²
- Choking spells and/or vomiting
- Momentary loss of consciousness (due to lack of oxygen)
- Slight fever

Pertussis can have serious consequences, including pneumonia, seizures, brain damage (due to stopped breathing), and even death. In fact, 80% of pertussis deaths occur in infants under 6 months of age.³ It may take up to 4 weeks before the symptoms start to get better, and full recovery can take several more weeks.¹

The bacteria that cause pertussis are found in an infected person's nose and throat. The disease can be easily spread by close contact with an infected person who is coughing.^{1,2}

Pertussis doesn't start with a loud cough

The disease starts with symptoms similar to a common cold. After about 10 to 12 days, the coughing becomes severe. In children between 6 months and 7 years of age, coughing fits are often followed by a "whoop" sound. This sound is less common in very young infants, adolescents, and adults.¹

Please see the additional Important Safety Information enclosed.

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Pertussis—a disease on the rise

Reported cases of pertussis are at a 45-year high^{4,5}

In 2004, there were nearly 25,827 cases of pertussis reported to the United States Centers for Disease Control and Prevention (CDC).⁵ This is a 122% increase over the number of reported cases in 2003—and a 25.6-fold increase from 28 years ago, when the number of cases was at its lowest (1010 cases in 1976).^{5,6} What is even more striking is the fact that reported cases of pertussis in people over the age of 15 have increased 452% during the 10 years 1994 through 2003.^{4,6}

Pertussis and your infant's health

When looking at the increase in reported pertussis cases in adolescents and adults, it is important to realize how this impacts infants. A CDC survey found that nearly half of all infants who contract pertussis end up in the hospital. Some infants may encounter complications such as pneumonia and seizures.⁷ Even more frightening is the fact that 80% of pertussis deaths occur in infants under 6 months of age.³

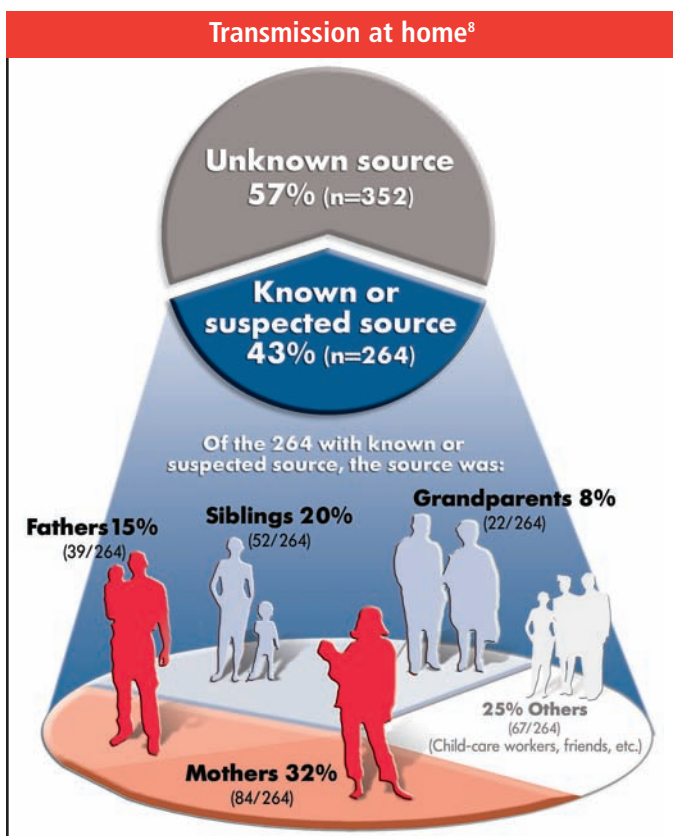
A family member can be the cause of infant pertussis

There is great interest in determining what role family members play in transmitting pertussis to infants and others in the household. In a CDC study of 774 reported cases of infant pertussis, interviews were conducted in 616 of the families to determine the source of the disease.⁸ A source was defined as a person with a serious cough who had contact with one of the infants in the study 7 to 20 days before the infant began coughing.⁸ The source was identified for 43% (264) of the infants with pertussis.⁸ Within this subgroup of 264 infants,

the known or suspected source of pertussis was⁸:

- The Mother in 32% of these infant cases
- A Dad in 15% of these infant cases
- A Sibling (≤ 4 to 19 years of age) in 20% of these infant cases

It is unknown whether immunizing adolescents and adults against pertussis will reduce the risk of transmission to infants.⁸



Please see the additional Important Safety Information enclosed.



Vaccination— the key to pertussis protection

How vaccines work

Vaccines “teach” the immune system how to recognize and fight bacteria and viruses before an infection happens. By giving the body a small “sample” of the germ, it can develop resistance without actually getting the disease.

Pertussis vaccination is not just for children anymore

Until recently, vaccination against pertussis was only available to infants and young children. However, the protective effects of diphtheria, tetanus and acellular pertussis (DTaP) vaccine are thought to wear off, leaving adolescents and adults susceptible to pertussis.

Fortunately, there is now a tetanus, diphtheria, and pertussis (Tdap) vaccine available for adults and adolescents aged 11 to 64 years. This vaccine, ADACEL™ (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed), is very similar to the one given to infants and children, but has been designed specifically to protect adolescents and adults from pertussis.

Make the decision that is right for you and your family

Now that you have learned more about pertussis and understand the role immunization plays in protecting you and your family, talk to your health-care professional to see whether getting a vaccination with ADACEL vaccine is right for you. For more information, please visit our Web site at www.ADACELVACCINE.com.

Important Safety Information

ADACEL vaccine is indicated for active booster immunization for the prevention of tetanus, diphtheria, and pertussis as a single dose in people 11 through 64 years of age.

As with any vaccine, ADACEL vaccine may not protect 100% of people receiving the vaccine. There are risks associated with all vaccines. The most common local side effects with ADACEL vaccine were injection site pain, redness, and swelling. The most common systemic side effects were headache, body ache, tiredness, and fever. 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. When administering an intramuscular injection like ADACEL vaccine in people with bleeding disorders, caution should be exercised because they may develop a serious bruise or collection of blood at the injection site. If you notice any other problems or symptoms following vaccination, please contact your health-care professional immediately.

Please see the additional Important Safety Information enclosed.

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 adolescents and adults between the ages of 11 and 64 years.

Who should not receive ADACEL vaccine?

- ADACEL vaccine should not be administered to anyone under the age of 11 or above the age of 64 years.
- 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 (collection of blood) where the vaccine is injected.
- Women who are pregnant or nursing.

How is ADACEL vaccine administered?

A single dose of ADACEL vaccine is injected into the muscle of the upper arm of persons ages 11 through 64 years. 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. Common systemic side effects include headache, body ache, 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-phenoxyethanol 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**.

This information is based on the ADACEL full Prescribing Information dated June 2005.

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**Help your family and
yourself stay protected.**

*Ask your health-care professional about
pertussis protection today!*

 **Adacel™**

Tetanus Toxoid, Reduced
Diphtheria Toxoid and Acellular
Pertussis Vaccine Adsorbed

Arming More People Against Pertussis

References: 1. MedlinePlus. Pertussis. Available at: <http://www.nlm.nih.gov/medlineplus/ency/article/001561.htm>. Accessed May 26, 2005. 2. Centers for Disease Control and Prevention (CDC). Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Hamborsky J, McIntyre L, Wolfe S, eds. 8th ed. Washington DC: Public Health Foundation, 2005. 3. Vitek CR, Pascual FB, Baughman AL, Murphy TV. Increase in deaths from pertussis among young infants in the United States in the 1990s. *Pediatr Infect Dis J*. 2003;22:628-634. 4. CDC. Summary of notifiable diseases—United States, 1994. Published Oct. 6, 1995, for *MMWR*. 1994;43(53):10. 5. CDC. Notice to readers: Final 2004 reports of notifiable disease. *MMWR*. 2005;54(81):770-780. 6. CDC. Summary of notifiable diseases—United States, 2003. Published April 22, 2005, for *MMWR*. 2003;52(54):28, 72. 7. CDC. Pertussis—United States, 1997-2000. *MMWR*. 2002;51(4):73-76. 8. Bisgard KM, Pascual FB, Ehresmann KR, et al. Infant pertussis: Who was the source? *Pediatr Infect Dis J*. 2004;23:985-989.

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