

PATIENT INFORMATION

DAPTACEL®

Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed

R_x only

Read this information carefully before your child receives this vaccine.

- This information is a summary and does not list all the possible benefits and risks of DAPTACEL vaccine. It does not take the place of talking with your child's doctor or other health-care provider
- Ask your child's doctor or health-care provider for a copy of the Vaccine Information Sheet from the Centers for Disease Control and Prevention (CDC)

What is DAPTACEL vaccine?

DAPTACEL vaccine is given to children to prevent the three serious diseases listed below. DAPTACEL vaccine works by causing the body to make its own protection (antibodies) against these diseases*:

- **Diphtheria:** Diphtheria can infect the throat, causing a thick covering that puts out a poison that can lead to problems with breathing, paralysis, heart failure, and sometimes even death
- **Tetanus:** The tetanus (lockjaw) germ enters the body through cuts, scratches, or wounds in the skin. Tetanus may cause a painful tightening of the muscles, seizures, and even death. It can also lead to "locking" of the jaw, preventing that person from opening his or her mouth or swallowing
- **Pertussis:** Pertussis (whooping cough) is a highly infectious disease, which means it is easily spread. It causes severe spells of coughing that may interfere with normal breathing. The coughing is often accompanied by a "whooping" sound. Pertussis can also cause pneumonia, seizures, brain damage, and even death

***Note:** The vaccine cannot cause any of these diseases.

Why should your child receive this vaccine?

Vaccination is the best-known way to protect your child against the following serious illnesses: diphtheria, tetanus, and pertussis. DAPTACEL vaccine may not protect 100% of the people who get the vaccine (especially people with immune system disorders), and it cannot be used to treat any of these diseases.

How is DAPTACEL vaccine given?

Your child should receive a total of four injections in the first two years of life: three in the first six months and another toward the middle of the second year of life. If your child misses one of the scheduled injections, talk with your child's doctor or health-care provider and schedule another visit as soon as possible. **It is important to make sure your child receives all four injections; otherwise, your child will not be fully immunized against these diseases.**

What to tell your child's doctor or health-care provider before your child receives DAPTACEL vaccine:

- **Before your child receives DAPTACEL vaccine, you must tell your doctor or health-care provider if your child:**
 - Is younger than 6 weeks or older than 6 years of age
 - Previously had any allergic reaction to DAPTACEL vaccine or any of the ingredients in this vaccine, which also includes latex from the vial stopper (see section describing ingredients)
 - Had a life-threatening allergic reaction to any vaccine that protects against diphtheria, tetanus, or pertussis in the past
 - Had symptoms of a brain or nervous system disorder after receiving a vaccine that contained pertussis
- **Also, tell your doctor or health-care provider if your child:**
 - Has a tendency to have seizures
 - Had a syndrome called Guillain-Barré after receiving a vaccine that contained tetanus toxoid

- Has a problem with bleeding, or bruises easily
- Has a moderate or severe illness with or without a fever. Talk to your child's doctor or health-care provider about this first, as minor illnesses may not be a problem
- Is taking any medications or has recently been given any other vaccine

What are the possible side effects of DAPTACEL vaccine?

The most common side effects that DAPTACEL vaccine might cause are:

- Soreness, redness, or swelling at the site of injection
- Fever, fussiness, or crying more than usual

These side effects usually clear up within a few days. Other less common side effects may also occur. If these events continue or become severe, tell your child's doctor or health-care provider.

Please tell your doctor or health-care provider if your child:

- Had any of the following problems after a dose of DAPTACEL vaccine or any other vaccine that protects against pertussis:
 - A high temperature (105°F or higher) within 48 hours after receiving the vaccine
 - Collapse or a shock-like state within 48 hours after receiving the vaccine
 - Constant crying that lasted 3 or more hours within 48 hours after receiving the vaccine
 - Seizures with or without a fever within 3 days after receiving the vaccine

Please be aware of the following other side effects that 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 your child experiences any of these signs, speak to your child's doctor or health-care provider and seek treatment right away. These reactions are rare and usually occur before leaving the doctor's office.

Brain or nervous system illnesses, collapse or periods of unconsciousness or lack of awareness, and seizures have occurred with other pertussis vaccines. Rarely, other serious events have been reported after vaccination with some pertussis vaccines; however, these risks are extremely uncommon.

If you notice any other problems or symptoms following vaccination, please inform your child's doctor or health-care provider immediately.

What are the ingredients of DAPTACEL vaccine?

DAPTACEL vaccine contains these ingredients:

- Noninfectious proteins from diphtheria, tetanus, and pertussis bacteria
- 2-phenoxyethanol (not as a preservative), sodium chloride (salt), aluminum, and aluminum salts
- Low levels of formaldehyde and glutaraldehyde

The stopper to the vial of this product contains latex that may cause allergic reactions.

For more information about DAPTACEL vaccine, talk to your child's doctor or health-care provider.

This information is based on the DAPTACEL vaccine full Prescribing Information dated March 2003.

Manufactured by:
Sanofi Pasteur Limited
Toronto Ontario Canada

MKT13128-1R

Distributed by:
Sanofi Pasteur Inc.
Swiftwater PA 18370 USA

Printed in USA
R4-1205 USA
D72-372MQ
2022392-253

sanofi pasteur

The vaccines business of sanofi-aventis Group