

# DTAP

## CDC RECOMMENDS 5 DOSES AT AGES 2/4/6/15 MONTHS AND 4 YEARS OLD

### INFRANRIX can cause:

- + Encephalopathy
- + Syncope (fainting)
- + Cellulitis
- + **Bronchitis**
- + Lymphadenopathy
- + Thrombocytopenia
- + **Sudden Infant Death Syndrome (SIDS)**
- + Anaphylactic reaction
- + Hypersensitivity
- + Hypotonia (floppy infant syndrome)
- + **Respiratory tract infection**
- + Ear pain
- + Cyanosis (blue skin)
- + Apnea
- + Angioedema (swelling)
- + Erythema
- + Pruritus (chronic itching)
- + **Urticaria (hives)**

### DAPTACEL can cause:

- + Lymphadenopathy
- + Cyanosis (blue skin)
- + Nausea
- + **Diarrhea**
- + Cellulitis
- + Injection site abscess
- + Hypersensitivity
- + **Screaming**
- + Syncope (fainting)
- + Somnolence (sleepiness)
- + Hypotonia (floppy infant syndrome)
- + HHE
- + Anaphylactic reaction: edema, face edema, swelling face, pruritus (chronic itching), rash generalized
- + Erythematous, macular, maculopapular
- + **Convulsions:** febrile convulsion, grand mal convulsion, partial seizures



Why is Sudden Infant Death Syndrome (SIDS) listed as an adverse reaction?

SOURCES FROM FDA + SANOFI + GLAXOSMITHKLINE

## SIDS

Sudden infant death syndrome (SIDS) is the unexplained death, usually during sleep, of a seemingly healthy baby less than a year old. SIDS is sometimes known as crib death because the infants often die in their cribs.

Although the cause is unknown, it appears that SIDS might be associated with defects in the portion of an infant's brain that controls breathing and arousal from sleep.

SIDS is listed as a potential reaction on a CDC recommended product administered four times before a child turns one. However, the CDC states on its website that SIDS has not been shown to be caused by vaccines even though it is listed by the manufacturer on the insert.



**Vaccines have not been shown to cause sudden infant death syndrome (SIDS).**

[cdc.gov/vaccinesafety/concerns/sids.html](https://cdc.gov/vaccinesafety/concerns/sids.html)

The manufacturer also instructs healthcare providers to inform parents or guardians "the potential for adverse reactions that have been temporally associated with administration of Infanrix or other vaccines containing similar components."

### 17 PATIENT COUNSELING INFORMATION

Provide the following information to the parent or guardian:

- Inform about the potential for adverse reactions that have been temporally associated with administration of INFANRIX or other vaccines containing similar components.
- Instruct to report any adverse events to their healthcare provider.

Are healthcare providers following the manufacturer instructions and informing parents the potential for Sudden Infant Death Syndrome after getting the DTAP shot? Or any of the other adverse reactions?

[fda.gov/media/75157/download](https://www.fda.gov/media/75157/download)

## BREATHING ADVERSE REACTIONS

**Bronchitis** is when the tubes that carry air to your **lungs**, called the bronchial tubes, get inflamed and swollen. You end up with a nagging **cough** and **mucus**.

Acute respiratory infection is an infection that may interfere with normal breathing. It can affect just your **upper respiratory system**, which starts at your **sinuses** and ends at your vocal chords, or just your **lower respiratory system**, which starts at your vocal chords and ends at your lungs.

**Anaphylaxis** causes your immune system to release a flood of chemicals that can cause you to go into shock — your blood pressure drops suddenly and your airways narrow, blocking breathing. Signs and symptoms include a rapid, weak pulse; a skin rash; and nausea and vomiting. Common triggers include certain foods, some medications, insect venom and latex.

**Syncope** is a sudden, temporary loss of consciousness, followed by a fall from a standing or sitting position. A **syncope** episode is usually short. What causes **syncope**? **Syncope** is caused by a decrease in blood flow to the brain. When blood flow to the brain decreases, oxygen to the brain also decreases. Any of the following conditions may cause ...

## HYPOTONIA

Hypotonia is a medical word for low muscle tone. If your baby has it, she will likely feel limp in your arms, like a rag doll. That's why it's also called floppy infant syndrome.





# CYANOSIS

Cyanosis is the bluish or purplish discoloration of the skin or mucous membranes due to the tissues near the skin surface having low oxygen saturation.

We are told not leave blankets in the crib, that back is best, and to never let a baby sleep in a lounger. Would the risk of cyanosis also be cause for concern?



# SKIN REACTIONS

Cellulitis (sel-u-LIE-tis) is a common, potentially serious bacterial skin infection. The affected skin appears swollen and red and is typically painful and warm to the touch.



Angioedema is a form of swelling in the deep part of the skin's inner layer and below, and it may become severe. In some cases, this swelling occurs along with the appearance of hives. This is why angioedema is sometimes referred to as "giant hives."

# ENCEPHALOPATHY + HYPERSENSITIVITY

Encephalopathy means brain disease, disorder, or damage. The term refers to temporary or permanent conditions that affect the brain's structure or function.

Hypersensitivity refers to undesirable reactions produced by the normal immune system, including allergies and autoimmunity. They are usually referred to as an over-reaction of the immune system and these reactions may be damaging, uncomfortable, or occasionally fatal.

Pertussis can lead to brain damage left untreated. Yet, this product also carries with it the risk of brain damage.



## LET'S DIG DEEPER ON PERTUSSIS

The manufacturer insert contains the following:

### **12 CLINICAL PHARMACOLOGY**

#### **12.1 Mechanism of Action**

##### **Pertussis**

Pertussis (whooping cough) is a respiratory disease caused by *B pertussis*. This Gram-negative coccobacillus produces a variety of biologically active components, though their role in either the pathogenesis of, or immunity to, pertussis has not been clearly defined.

If the role of immunity to Pertussis is not clearly defined, then how does the manufacturer know the DTAP shot will provide protection to the patient?