Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed

**INDICATIONS AND USAGE**

ADACEL vaccine should not be administered into the buttocks nor by the intradermal route, since these methods of administration may be associated with local reactions that are more severe than those normally associated with the intramuscular route. SHAKE THE VIAL WELL to distribute the suspension uniformly before withdrawing the 0.5 mL dose for intramuscular administration.

**CONTRAINDICATIONS**

Anaphylactic reactions and other severe allergic reactions (eg, severe local reactions associated with systemic symptoms) following a prior dose of tetanus toxoid usually have occurred within 28 days; an acute complication or sequelae (including death) of an illness, disability, injury, or condition referred to as a systemic reaction following ADACEL vaccine were similar to those reported in the four principal trials in the US with the exception that the events occurring in approximately 80% of all subjects. Headache was the most frequently reported systemic event occurring in approximately 80% of all vaccinees. In addition, overall rates of pain were higher in adolescent recipients of ADACEL vaccine than in adult recipients. However, the rates of pain did not significantly differ for adults.

**ADVERSE REACTIONS**

The following are all adverse events reported for ADACEL vaccine in four principal trials: pain, redness, swelling, tenderness, warmth, induration, injection site reaction, erythema, itching, local reaction, eczema, phlebitis, and cellulitis. The following are all adverse events reported for ADACEL vaccine in four principal trials: pain, redness, swelling, tenderness, warmth, induration, injection site reaction, erythema, itching, local reaction, eczema, phlebitis, and cellulitis.

**Local Reactions**

Local reactions that have been reported following ADACEL vaccination are pain, redness, warmth, and tenderness. The frequency of local reactions reported in controlled clinical trials was generally higher in adolescents compared to adults. Local reactions, particularly pain, were reported more frequently following the intramuscular administration of ADACEL vaccine relative to the subcutaneous administration of tetanus toxoid and diphtheria toxoid. The local reactions occurring in the ADACEL vaccine group were similar to those reported in the concurrent control group. The frequency of local reactions reported in controlled clinical trials was generally higher in adolescents compared to adults. Local reactions, particularly pain, were reported more frequently following the intramuscular administration of ADACEL vaccine relative to the subcutaneous administration of tetanus toxoid and diphtheria toxoid. The local reactions occurring in the ADACEL vaccine group were similar to those reported in the concurrent control group. The frequency of local reactions reported in controlled clinical trials was generally higher in adolescents compared to adults. Local reactions, particularly pain, were reported more frequently following the intramuscular administration of ADACEL vaccine relative to the subcutaneous administration of tetanus toxoid and diphtheria toxoid. The local reactions occurring in the ADACEL vaccine group were similar to those reported in the concurrent control group.

**Systemic Reactions**

Systemic reactions that have been reported following ADACEL vaccination are headache, malaise, myalgia, nausea, vomiting, and fever. The frequency of systemic reactions reported in controlled clinical trials was generally higher in adolescents compared to adults. Systemic reactions, particularly headache, were reported more frequently following the intramuscular administration of ADACEL vaccine relative to the subcutaneous administration of tetanus toxoid and diphtheria toxoid. The systemic reactions occurring in the ADACEL vaccine group were similar to those reported in the concurrent control group.

**Pregnancy**

ADACEL vaccine is not indicated for use in pregnant women. If ADACEL vaccine is accidentally administered to a pregnant woman, there are no available data to suggest that ADACEL vaccine will cause fetal harm or that the occurrence of adverse events following ADACEL vaccination will result in a miscarriage. Women should be advised to avoid becoming pregnant for at least 1 month after ADACEL vaccination.

**Nursing Mothers**

ADACEL vaccine may be used in nursing mothers. However, because many vaccines contain preservatives, it is preferable to defer vaccination of the nursing mother until the infant is no longer breast-feeding. The mother should be informed of the potential for adverse reactions to be transmitted to the infant through breast milk.

**Local and Systemic Reactions when Given with Hepatitis B Vaccine**

The following adverse events have been spontaneously reported during the post-marketing use of ADACEL:

- Fever
- Painful reaction to injection site
- Swelling
- Headache
- Myalgia
- Fatigue
- Nausea
- Vomiting
- Rash
- Itching
- Malaise
- Generalized weakness
- Asthenia
- Myalgia
- Lethargy
- Convulsion
- Anaphylaxis

Event rates were similar in the two groups until 36 months, at which point they diverged sharply.

**REFERENCES**


